

1

2

3

4

5

6

APPLICATION FOR LETTRES PATENT

8

9 BE IT KNOWN that Michael Nissenbaum, Ducksoo Kim and Andy H. Levine have
10 made a new and useful improvement entitled "DEVICES, SYSTEMS AND METHODS
11 FOR CREATING SUTURELESS ON-DEMAND VASCULAR ANASTOMOSES AND
12 HOLLOW ORGAN COMMUNICATION CHANNELS".

13

14

PROVISIONAL PATENT APPLICATION

This invention was first filed as a Provisional Patent Application on December 9, 1999 as U.S. Application Serial No. 60/169,874.

FIELD OF THE INVENTION

The present invention is concerned generally with minimally invasive methods for accessing the vascular system and hollow organs of the body; and is directed to an assembly and methodology for creating sutureless vascular anastomoses and hollow organ communication channels on-demand.

BACKGROUND OF THE INVENTION

Coronary artery disease is the single leading cause of human mortality and is annually responsible for over 900,000 deaths in the United States alone. Additionally, over 3 million Americans suffer chest pain (angina pectoris) because of it. Typically, the coronary artery becomes narrowed over time by the build up of fat, cholesterol and blood clots. This narrowing of the artery is called arteriosclerosis; and this condition slows the blood flow to the heart muscle (myocardium) and leads to angina pectoris due to a lack of nutrients and adequate oxygen supply. Sometimes it can also completely stop the blood flow to the heart causing permanent damage to the myocardium, the so-called "heart attack."

The conventional treatment procedures for coronary artery disease vary with the severity of the condition. If the coronary artery disease is mild, it is first treated with diet

1 and exercise. If this first course of treatment is not effective, then the condition is treated
2 with medications. However, even with medications, if chest pain persists (which is usually
3 secondary to development of serious coronary artery disease), the condition is often treated
4 with invasive procedures to improve blood flow to the heart. Currently, there are several
5 types of invasive procedures: (1) Catheterization techniques by which cardiologists use
6 balloon catheters, atherectomy devices or stents to reopen up the blockage of coronary
7 arteries; or (2) Surgical bypass techniques by which surgeons surgically place a graft
8 obtained from a section of artery or vein removed from other parts of the body to bypass
9 the blockage.

10 Conventionally, before the invasive procedures are begun, coronary artery
11 angiography is usually performed to evaluate the extent and severity of the coronary artery
12 blockages. Cardiologists or radiologists thread a thin catheter through an artery in the leg
13 or arm to engage the coronary arteries. X-ray dye (contrast medium) is then injected into
14 the coronary artery through a portal in the catheter, which makes the coronary arteries
15 visible under X-ray, so that the position and size of the blockages in the coronary arteries
16 can be identified. Each year in U.S.A., more than one million individuals with angina
17 pectoris or heart attack undergo coronary angiographies for evaluation of such coronary
18 artery blockages. Once the blocked arteries are identified, the physician and surgeons then
19 decide upon the best method to treat them.

20 In the surgical correction of vascular disease in the human body, it is frequently
21 necessary to attach blood vessels to each other. A native blood vessel may be diseased
22 with conditions that cause blockages, such as atherosclerosis. In this situation, it is

1 frequently necessary to reroute the blood that would ordinarily traverse the diseased vessel
2 via the creation of a vascular bypass. The conduit used to form this bypass around an
3 obstructed segment may be another blood vessel native to the patient, such as a vein or
4 artery harvested from elsewhere in the body; or may be a man-made conduit of either
5 synthetic or biological material. Methods for attaching blood vessels to each other include:
6 end to end attachments, where the result is a linear conduit for blood flow with the
7 bypassing vessel and the vessel to which it is attached lying in parallel, in-line with each
8 other; side to side attachments, where the result is a staggered, linear channel, where the
9 bypassing vessel and the vessel to which it is attached are in parallel but offset by the width
10 of one of the blood vessels; and end to side attachments, where the bypassing vessel meets
11 the vessel which it is to supply with flow at some angle of less than 180 degrees, and
12 typically approximately 90 degrees and often as a 'T' or 'L' or 'H' type of connection.

13 It is useful here to understand in depth what the traditional coronary arterial bypass
14 entails and demands both for the patient and for the cardiac surgeon. In a standard
15 coronary bypass operation, the surgeon must first make a foot-long incision in the chest
16 and split the breast bone of the patient. The operation requires the use of a heart-lung
17 machine that keeps the blood circulating while the heart is being stopped and the surgeon
18 places and attaches the bypass grafts. To stop the heart, the coronary arteries also have to
19 be perfused with a cold potassium solution (cardioplegia). In addition, the body
20 temperature of the patient is lowered by cooling the blood as it circulates through the heart-
21 lung machine in order to preserve the heart and other vital organs. Then, as the heart is
22 stopped and a heart-lung machine pumps oxygenated blood through the patient's body, the

1 surgeon makes a tiny opening into the front wall of the target coronary artery with a very
2 fine knife (arteriotomy); takes a previously excised saphenous vein (a vein from a leg) or
3 an internal mammary artery (an artery from the chest); and sews the previously excised
4 blood vessel to the coronary artery. Synthetic substitutes for a naturally occurring blood
5 vessel are available and often used.

6 To create the anastomosis at the aorta, the ascending thoracic aorta is first partially
7 clamped using a curved vascular clamp to occlude the proper segment of the ascending
8 aorta; and a hole is then created through the front wall of the aorta to anchor the vein graft
9 (or synthetic substitute) with sutures. The graft bypasses the blockage in the coronary
10 artery and restores adequate blood flow to the heart. After completion of the grafting, the
11 patient is taken off of the heart-lung machine and the patient's heart starts beating again.
12 Most of the patients can leave the hospital in about 6 days after the surgical procedure.

13 It will be noted that coronary artery bypass surgery is considered a definitive
14 method for treating coronary arterial disease because all kinds of obstructions cannot be
15 treated by angioplasty; and because a recurrence of blockages in the coronary arteries even
16 after angioplasty is not unusual. Also coronary artery bypass surgery usually provides for
17 a longer patency of the grafts and the bypassed coronary arteries in comparison with the
18 results of an angioplasty procedure. However, traditional coronary artery bypass surgery
19 is a far more complicated procedure, having need of a heart-lung machine and a stoppage
20 of the heart. Also, it is a more invasive procedure and is more expensive to perform.
21 Therefore, cardiac surgeons have recently developed an alternative to the standard bypass
22 surgery, namely "minimally invasive bypass operation" (MIBO) in order to reduce the

1 risks and the cost associated with the surgery. Also, the MIBO is performed without use of
2 a heart-lung machine or the stopping of the heart. Some of the current methods for
3 creating these connections include handsewn surgical anastomoses, where a surgeon places
4 a series of surgical knots around the circumference of the vascular connection, forming a
5 liquid-tight connection; as well as a variety of vascular staple type devices, where
6 mechanical apparatus are used to effect the connection, generally using a two or more part
7 apparatus comprising the staple introducer and an 'anvil' type of part against which the
8 staples are curved back, bent, or otherwise fixed into position around the circumference of
9 the vascular connection.

10 Another approach has been the introducer catheter based methods and apparatus for
11 the creation of an end-to-side vascular connection (anastomosis) using an implanted device
12 comprising a deformable flange or retained portion and deformable flange, to which a
13 biological or synthetic conduit has been pre-attached ex-vivo; and a variety of
14 configurations for introducer mechanisms and systems for inserting this implantable device
15 into the side of the blood vessel. For the purposes of this description, the blood vessel is
16 generally defined as the blood vessel which is punctured and which receives the collar or
17 deformable flange portion of the implantable device into its internal lumen. The receiving
18 blood vessel may be either the source or the recipient of blood flow, depending on the
19 required and existing direction of blood flow. Merely illustrative and representative of
20 these introducer catheter based vascular bypass graft systems and techniques are U.S.
21 Patent Nos. 6,007,544; 5,797,920, and 5,676,670 all of which describe a catheter
22 apparatus and methods for creating a bypass on-demand between an unobstructed and

1 obstructed blood vessel using a deformable cuff connector and graft segment in tandem; as
2 well as Nos. 6,036,702; 6,013,190; 6,001,124; 5,972,017; 5,941,908; and 5,931,842
3 which illustrate a range and variety of T-shaped, L-shaped, H-shaped, and oblique-angle
4 graft connectors available for medical use.

5 A key advantage of the methods and devices described in these issued U.S. Patents
6 is the ability to create a vascular anastomosis while maintaining high blood pressures
7 (systemic and greater) within the receiving blood vessels. These devices and systems
8 therefore allow the creation of the proximal anastomosis in Coronary Artery Bypass
9 Grafting procedures (CABG) to be performed without need to exclude blood from the aorta
10 where the site of anastomosis is to be. This in turn obviates the need for use of the
11 cardiopulmonary bypass machine, a device (which takes over the pumping of the blood
12 through the body while the proximal aorta is made blood pressure free); and eliminates the
13 Aortic Side Biting Clamp, a semicircular clamp which pinches off a portion of the aorta,
14 creating a blood pressure free pocket to which the handsewn graft attachment was
15 previously made. Use of both the machine and the side biting clamp result in trauma to the
16 aorta; and such trauma causes, among other things, the release of embolic debris from the
17 aortic wall (a cause of stroke, cognitive deterioration, and other morbidities), and/or
18 damage to the lining of the aorta which can result in separation of the layers of the aorta,
19 resulting in dissection, a potentially lethal complication. Frequently also, the time required
20 for surgery is shortened because intricate in-vivo suturing techniques are not required to
21 ensure acceptable patency rates and no leakage at the handsewn anastomoses of the new
22 grafts.

1 There remains, however, a long-standing and continuing need for additional
2 improvements in bypass technique and apparatus which would allow surgeons to perform
3 more simple multiple bypass procedures in a minimally invasive way using tubular grafts as
4 vascular shunts; and, in particular, a need remains for a catheterless method to place one or
5 more vein grafts or other conduits proximally to the aorta and distally to the coronary
6 artery without using a heart-lung machine, and without stopping the heart, and without
7 using the side biting clamp.

8 In addition to the foregoing difficulties, there exists also a very different medical
9 problem in the non-vascular realm, in particular with regard to obtaining in-vivo access to
10 a hollow organ within the body of a living subject.

11 Access to the interior of a hollow organ is often needed for a number of reasons,
12 depending on the organ system. These accesses may be required to supply food substances
13 into the stomach or small bowel in patients who are unable to eat (gastrostomy and
14 jejunostomy, respectively); and/or to eliminate wastes or the buildup of pressure in other
15 organs whose outlets are blocked or dysfunctional, as may occur in the obstructed urinary
16 system (nephrostomy or cystostomy), respiratory system (tracheostomy), or the
17 pathologically dilated cecum (proximal large bowel and cecostomy). Occasionally, a
18 hollow organ space or body cavity is filled with infected material, and it is clinically
19 desirable to create a communication channel allowing the infected contents to be drained
20 rather than surgically removing the infected organ. Such a situation may occur within the
21 gallbladder, and the communication channel so created is then called a cholecystostomy.
22 Occasionally, a communication channel is required between hollow body cavities, such as

1 between a cyst originating in the pancreas, and the inside of the stomach. Periodically as
2 well, a communication channel is required into a spatial area or zone within the body, such
3 as the peritoneal cavity, in order to instill fluids for dialysis. Thus, a number of different
4 devices and systems now exist for the on-demand creation of these types of communication
5 channels between hollow organs; or between body cavities and the skin surface; or between
6 two hollow organs within the body.

7 It will be noted that many hollow organ surgical procedures are now performed
8 using trocars and cannulas. Originally these devices were used for making a puncture and
9 leaving a tube to drain fluids. As technology and surgical techniques advanced, it became
10 possible to insert surgical instruments through the cannulas to perform invasive procedures
11 through openings less than half an inch in diameter, whereas in the past these procedures
12 required incisions of many inches. By using a trocar and minimizing the incision, the
13 stress and loss of blood suffered by patients was reduced. A range and variety of trocar
14 assemblies are known. These are represented by U.S. Patent Nos. 4,601,710; 5,545,150;
15 5,122,122; 5,112,321; and 6,063,099.

16 Today, surgical trocars are most commonly used in laparoscopic surgery. Prior to
17 use of the trocar, the surgeon will usually introduce a Veress needle into the patient's
18 abdominal cavity. The Veress needle has a stylet which permits the introduction of gas
19 into the abdominal cavity. After the Veress needle is properly inserted, it is connected to a
20 gas source and the abdominal cavity is insufflated to an approximate abdominal pressure of
21 15 mm Hg. By insufflating the abdominal cavity, pneumoperitoneum is created separating
22 the wall of the body cavity from the internal organs.

1 A trocar is then typically used to puncture the body cavity. The piercing tip or
2 obturator of the trocar is inserted through the cannula; and the cannula partially enters the
3 body cavity through the incision made by the trocar. The obturator is then removed from
4 the cannula. An elongated endoscope or camera may be then inserted through the cannula to
5 view the body cavity; or surgical instruments may be inserted through the cannula to
6 perform ligations or other procedures.

7 A great deal of force is often required to cause the obturator to pierce the wall of
8 the body cavity. When the piercing tip breaks through the cavity wall, resistance to
9 penetration ceases and the tip may reach internal organs or blood vessels, with resultant
10 lacerations and potentially serious injury. For this reason, a variety of trocar designs have
11 been developed with spring loaded shields surrounding the piercing tip of the obturator.
12 Once the piercing tip of the obturator has completely pierced the body cavity wall, the
13 resistance of the tissue to the spring loaded shield is reduced and the shield springs forward
14 into the body cavity and covers the piercing tip. The shield thereby protects internal body
15 organs and blood vessels from incidental contact with the piercing tip and resultant injury.
16 Such trocars including various safety shield designs are illustrated by U.S. Patent Nos.
17 4,535,773; 4,654,030; and 4,601,710; 5,104,382; 4,902,280; 5,030,206; 5,545,150; and
18 5,350,393.

19 Clearly both the realms of performing vascular bypass graft procedures and
20 accessing the interior of a hollow organ can and would benefit from structural devices and
21 improved surgical methods which offer simplified means for joining a prepared
22 communication channel to a blood vessel or a hollow organ on-demand in a minimally

1 invasive way. Moreover, were such simplified means developed such that the presently
2 existing requirement and necessity of using a catheter or cannula is eliminated and avoided,
3 such an improvement would be generally recognized in the medical arts as a major advance
4 and unusual benefit to both the surgeon and his patient.

5

6 **SUMMARY OF THE INVENTION**

7 The present invention has multiple formats and applications. A first format is a
8 catheterless, piercing introducer assembly suitable for the introduction and sutureless
9 juncture of a prepared communication channel to the interior space of an anatomic body
10 part within a living subject, said introducer assembly comprising:

11 a perforator instrument comprised of

12 (i) at least one elongated supporting shaft of predetermined overall
13 dimensions and axial configuration,

14 (ii) a controlling handle attached at one end to said supporting shaft; and

15 (iii) a perforating headpiece integrally joined to the other end of said
16 supporting shaft, said perforating headpiece comprising a perforating tip, a penetrating
17 body, and a base aspect; and

18 communication channel controlling means disposed adjacent to said perforating
19 headpiece on said supporting shaft of said perforator instrument.

20

21 A second format is a catheterless, piercing introducer assembly suitable for the
22 introduction and sutureless juncture of a prepared communication channel to the interior

1 space of an anatomic body part within a living subject, said introducer assembly
2 comprising:

3 a perforator instrument comprised of

4 (i) at least one elongated supporting shaft of predetermined overall
5 dimensions and axial configuration
6 (ii) a controlling handle attached at one end to said supporting shaft; and
7 (iii) a perforating headpiece integrally joined to the other end of said
8 supporting shaft, said perforating headpiece comprising a perforating tip, a penetrating
9 body, and a base aspect.

10 communication channel controlling means disposed adjacent to said perforating
11 headpiece on said supporting shaft of said perforator instrument;

12 a volumetric sheath having two open ends and at least one sidewall of determinable
13 dimensions, said sheath being

14 (1) sized at one open end for on-demand placement adjacent to and
15 aligned closure with said perforating headpiece of said perforator instrument,
16 (2) substantially annular in configuration over its axial length, and
17 (3) adapted for protective positioning around and volumetric spatial
18 envelopment of at least a portion of said supporting shaft extending from said perforating
19 headpiece of said perforator instrument, said sheath providing a protective covering for
20 said enveloped spatial volume then surrounding said supporting shaft; and

21 position holding means attachable to and detachable from said volumetric sheath and
22 said supporting shaft of said perforator instrument for holding said volumetric sheath and

1 the enveloped spatial volume at a set position around said supporting shaft of said
2 perforator instrument.

3

4 A third format of the present invention is a catheterless, piercing introducer
5 assembly suitable for the introduction and sutureless juncture of a prepared communication
6 channel to the interior space of an anatomic body part within a living subject, said
7 introducer assembly comprising:

8 a perforator instrument comprised of

9 (i) at least one elongated supporting shaft of predetermined overall
10 dimensions and axial configuration

11 (ii) a controlling handle attached at one end to said supporting shaft; and

12 (iii) a perforating headpiece integrally joined to the other end of said
13 supporting shaft, said perforating headpiece comprising a perforating tip, a penetrating
14 body, and a base aspect;

15 communication channel controlling means disposed adjacent to said perforating
16 headpiece on said supporting shaft of said perforator instrument;

17 a volumetric sheath having two open ends and at least one sidewall of determinable
18 dimensions, said sheath being

19 (1) sized at one open end for on-demand placement adjacent to and
20 aligned closure with said perforating headpiece of said perforator instrument,

21 (2) substantially annular in configuration over its axial length, and

22 (3) adapted for protective positioning around and volumetric spatial

1 envelopment of at least a portion of said supporting shaft extending from said perforating
2 headpiece of said perforator instrument, said sheath providing a protective covering for
3 said enveloped spatial volume then surrounding said supporting shaft;

4 position holding means attachable to and detachable from said volumetric sheath and
5 said supporting shaft of said perforator instrument for holding said volumetric sheath and
6 the enveloped spatial volume at a set position around said supporting shaft of said
7 perforator instrument; and

8 prepared communication channel comprising

9 a linking connector including at least

10 a first portion of determined dimensions and configuration which is
11 deformable on-demand, said first portion of said linking connector being suitable for
12 passage through an aperture and deformation within the interior space of an anatomic body
13 part whereby said deformation serves to secure said communication channel to the interior
14 of the anatomic body part and places said secured communication channel in fluid flow
15 communication with the interior space of the anatomic body part, and

16 a second portion of determined dimensions and configuration which is

17 permanently joined to the sidewall of a tubular conduit such that said joining retains and
18 secures the tubular conduit for fluid flow communication; and

19 a tubular conduit of fixed dimensions and configuration having two open ends and
20 at least one internal lumen, said tubular conduit being permanently joined at one open end
21 to said linking connector.

22

BRIEF DESCRIPTION OF THE FIGURES

The present invention may be better appreciated and more easily understood when taken in conjunction with the accompanying drawing, in which:

Fig. 1 is a perspective illustration of a first preferred embodiment of the introducer assembly comprising the present invention;

Figs. 2A and 2B are illustrations of the perforator instrument comprising a component part of the introducer assembly of Fig. 1;

Figs. 3A and 3B are illustrations of the volumetric sheath comprising a component part of the introducer assembly of Fig. 1;

Figs. 4A and 4B are illustrations of the position holding means comprising a component part of the introducer assembly of Fig. 1:

Fig. 5 is an illustration of the inter-relationship between the volumetric sheath of Figs. 3A and 3B and the position holding means of Figs. 4A and 4B:

Figs. 6A, 6B, and 6C are illustrations of a linking connector and tubular conduit which comprise a prepared communication channel to be used with the introducer assembly of Fig. 1:

Fig. 7 is an illustration of the inter-relationship between the prepared communication channel of Figs. 6B and 6C and the perforator instrument of Figs. 2A and 2B;

Figs. 8A and 8B are perspective and partial cross-sectional illustrations of the prepared communication channel of Figs. 6B and 6C when positioned within and part of the complete introducer assembly of Fig. 1;

1 Fig. 9 is an illustration of the complete introducer assembly of Figs. 8A and 8B
2 when approaching a sidewall of a blood vessel or hollow organ in-vivo;

3 Fig. 10 is an illustration of the complete introducer assembly after piercing and
4 penetrating through an aperture in the sidewall of a blood vessel or hollow organ;

5 Fig. 11 is an illustration of the advancement forward of the prepared
6 communication channel into the internal spatial volume of a blood vessel or hollow organ
7 using the complete introducer assembly;

8 Fig. 12 is an illustration of the deployment in-situ and the sutureless securing of the
9 prepared communication channel within the internal spatial volume of a blood vessel or
10 hollow organ;

11 Fig. 13 is an illustration of the partial rearward withdrawal of the introducer
12 assembly after the communication channel has been deployed and secured to a blood vessel
13 or hollow organ;

14 Fig. 14 is an illustration of the joined and secured communication channel after the
15 introducer assembly has been removed;

16 Fig. 15 is an illustration of one alternative embodiment for the perforating
17 headpiece of the perforator instrument of Fig. 2;

18 Fig. 16 is an illustration of a second alternative embodiment for the perforating
19 headpiece of the perforator instrument of Fig. 2;

20 Figs. 17A and 17B are cross-sectional and perspective illustrations of the
21 perforating headpiece of Fig. 16;

22

1 Fig. 18 is an illustration of one alternative embodiment for the volumetric sheath of
2 Fig. 3;

3 Fig. 19 is an illustration of the relationship between the prepared communication
4 channel of Fig. 6C when used in the perforating headpiece of Figs. 16 and 17 and the
5 volumetric sheath of Fig. 18;

6 Fig. 20 is an illustration of a second alternative embodiment for the volumetric
7 sheath of Fig. 3;

8 Fig. 21 is an illustration of one alternative embodiment of the introducer assembly
9 of Fig. 1;

10 Fig. 22 is a detail partial cross-sectional illustration of the alternative introducer
11 assembly of Fig. 21;

12 Fig. 23 is a perspective illustration of a second preferred embodiment of the
13 introducer assembly comprising the present invention;

14 Fig. 24 is an illustration of the perforator instrument comprising a component part
15 of the introducer assembly of Fig. 23;

16 Fig. 25 is an illustration showing details of the coaxial supporting shafts in the
17 perforator instrument of Fig. 24;

18 Fig. 26 is an illustration showing details of the perforating headpiece in the
19 perforator instrument of Fig. 24;

20 Fig. 27 is an illustration of the volumetric sheath comprising a component part of
21 the introducer assembly of Fig. 23;

22

1 Figs. 28A and 28B are illustrations of the communication channel controlling means
2 comprising part of the introducer assembly of Fig. 23;

3 Fig. 29 is a partial cross-sectional illustration of the prepared communication
4 channel of Fig. 6C positioned within the complete introducer assembly of Fig. 23;

5 Fig. 30 is a cross-sectional illustration of the complete introducer assembly of Fig.
6 29 after piercing and penetrating through an aperture in the sidewall of a blood vessel or
7 hollow organ;

8 Fig. 31 is an illustration of a deployment at will within the internal spatial volume
9 of a blood vessel or hollow organ and the securing of the communication channel to the
10 blood vessel or hollow organ;

11 Fig. 32 is an illustration of the partial rearward withdrawal of the introducer
12 assembly of Fig. 23 after the communication channel has been deployed and secured to a
13 blood vessel or hollow organ;

14 Fig. 33 is an illustration of the secured communication channel after the introducer
15 assembly of Fig. 23 has been removed;

16 Figs. 34A and 34B are illustrations of a first linking connector;

17 Figs. 35A and 35B are illustrations of a second linking connector;

18 Figs. 36A and 36B are illustrations of a third linking connector;

19 Figs. 37A and 37B are illustrations of a fourth linking connector;

20 Figs. 38A and 38B are illustrations of an unbranched tubular conduit;

21 Fig. 39 is an illustration of a multi-branched tubular conduit;

22 Figs. 40A and 40B are illustrations of a first type of tubular conduit construction;

1 Figs. 41A and 41B are illustrations of a second type of tubular conduit construction;

2 Figs. 42A and 42B are illustrations of a third type of tubular conduit construction;

3 Figs. 43A and 43B are illustrations of a fourth type of tubular conduit construction;

4 Fig. 44 is a cross-sectional illustration of a first style of internal lumen for a tubular

5 conduit;

6 Fig. 45 is a cross-sectional illustration of a second style of internal lumen for a

7 tubular conduit;

8 Fig. 46 is a cross-sectional illustration of a third style of internal lumen for a

9 tubular conduit; and

10 Fig. 47 is a cross-sectional illustration of a fourth style of internal lumen for a

11 tubular conduit.

12

13 DETAILED DESCRIPTION OF THE INVENTION

14 The present invention is an introducer assembly and surgical technique for creating

15 a single channel bypass or multiple channel bypasses on-demand between blood vessels

16 such as the aorta and an obstructed coronary artery in-vivo; and for creating an access

17 channel or duct to the interior space of a hollow organ in-vivo. The present invention can

18 utilize a synthetic tubular conduit as a communication channel; or a previously excised

19 vascular segment as a grafted tubular conduit; or any other biological conduit created via

20 hormonally or genetically modified cellular means. In addition, the invention employs a

21 catheterless introducer assembly and system in combination with the prepared

22 communication channel to create single or multiple conduit shunts or grafts in-vivo. The

1 grafted tubular conduit will then be used either to deliver blood from a primary blood
2 vessel, around the obstruction, into a secondary artery or vein in order to increase and/or
3 maintain proper blood circulation in the living body; or provide an access duct or portal
4 into a hollow organ in the body of a living subject. A number of substantial advantages
5 and major benefits are therefore provided by the present invention, some of which include
6 the following:

7 1. The present invention provides the means for surgeons to perform single or
8 multiple channel grafts in a minimally invasive manner. The methodology permits the
9 surgeon to utilize either synthetic tubular conduits as communication channels or previously
10 excised veins or arteries or other biological conduit as bypass grafts; and allows the
11 surgeon to place each of the tubular conduits from a primary unobstructed artery (such as
12 the aorta) to a secondary obstructed artery (such as the obstructed coronary artery) without
13 using a heart-lung machine and without need for stopping the heart during the surgery.

14 2. The present methodology also avoids the prior need to exclude blood from
15 the section of the primary vessel to which the graft is being attached. In the case of CABG
16 surgery, for example, there would be no further need for an aortic side biting clamp — a
17 device with rough semi-circular jaws that isolates a centrally located zone of the aorta from
18 the blood and blood pressure then present in the rest of the aorta.

19 3. The present invention simplifies the complexity of conventional vascular
20 bypass or hollow organ surgery and makes the surgery less invasive. Moreover, the
21 introducer assembly and technique provides the ability to create multiple communication
22 channels using a sutureless and catheterless procedure which not only shortens the

1 conventional operation time for surgery but also makes the surgery safer and more cost
2 effective.

3 4. The present invention is suitable for creating a single conduit graft or
4 multiple conduit grafts in any medical situation, condition, or pathology in which there is a
5 need for to direct blood flow to a specific blood vessel or vascular area or body region.
6 The cause or source of the medical problem may be an obstruction in a blood vessel; or a
7 narrowing or thickening of a blood vessel wall; or a diminution or narrowing of a vascular
8 section in a particular blood vessel. Each of these medical conditions has its particular
9 cause, origin, or source; and each of these pathologies, though different in origin, causes a
10 similar effect overall -- a loss of blood flow and blood pressure within the blood vessel.
11 Accordingly, the present invention is deemed useful and desirable to overcome any of these
12 particular medical conditions and instances where there is a demonstrated need for
13 increased blood pressure and blood volume flow within a particular blood vessel in the
14 body, and where that blood may be supplied from a suitable adjacent vessel using the
15 present system.

16 5. The present apparatus and methodology can be employed to create a bypass
17 conduit between any two blood vessels. In many instances, the bypass conduit will be
18 made between a primary unobstructed artery and a secondary obstructed artery, a typical
19 example being a bypass between the ascending aorta and an obstructed coronary artery.
20 However, a bypass shunt may also be created between any two veins (such as between the
21 portal vein and the inferior vena cava); or between an artery and a vein (such as between
22 the superior vena cava and a pulmonary artery) between the different chambers of the

1 heart, or between the heart chambers and blood vessels. Equally important, although the
2 primary focus of the present invention is the thoracic cavity and the recognized need for
3 bypass conduits among the blood vessels found therein, the present apparatus and
4 methodology may be employed anywhere in the human body where there is a need for
5 increased vascularization or revascularization of the local region. The sole limitation,
6 therefore, is a means of access for the catheter apparatus, the introducer system, and the
7 methodology to be performed by the skilled surgeon, or interventional radiologist, or other
8 medical specialist.

9 6. The introducer assembly and method of use provides on-demand duct access
10 to the interior of a hollow organ in a variety of applications. These grafted ducts provide
11 access to supply food substances into the stomach or small bowel in patients who are
12 unable to eat (gastrostomy and jejunostomy, respectively); and/or as a channel to eliminate
13 wastes or the buildup of pressure in other organs whose outlets are blocked or
14 dysfunctional, as may occur in the obstructed urinary system, respiratory system, or the
15 pathologically dilated. Also, when a hollow organ or cavity is filled with infected material,
16 the introducer system creates a communication channel for egress, thereby allowing the
17 infected contents to be drained rather than surgically removing the infected organ or cavity.
18 Such a situation typically occurs within the gallbladder and the communication channel so
19 created is then called a cholecystostomy. In addition, the system will provide a
20 communication channel between hollow body cavities, such as between a cyst originating in
21 the pancreas, and the inside of the stomach or between ventricles of brain and peritoneum
22 or vascular system; and when a communication channel is required to be placed into a

1 spatial area or zone within the body, such as the peritoneal cavity, in order to instill fluids
2 for dialysis.

3 In order to better appreciate and more clearly understand the introducer assembly
4 and the system of intended usage, the invention as a whole will be described as first and
5 second preferred embodiments which describe both the requisite and optional component
6 parts and subassemblies in detail; and also present a series of alternative embodiments and
7 features which can be optionally employed at will in addition to or in place of pertinent
8 parts in either of the preferred embodiments described herein.

9 **I. A First Preferred Embodiment**

10 A first preferred format and embodiment of the introducer assembly is exemplified
11 and illustrated by Figs. 1-14 respectively. As shown therein, Figs. 1-8 identify the
12 preferred introducer assembly in its minimal and optional component parts; while Figs. 9-
13 14 respectively illustrate the intended method of usage and system which uses the
14 introducer assembly to achieve a sutureless juncture of a prepared communication channel
15 to a blood vessel or to the interior of a hollow organ.

16 The introducer assembly as a whole is illustrated by Figs. 1 and 2. As seen therein,
17 the optimized introducer assembly is comprised of a perforator instrument 10; and the
18 communication channel controlling means 40 which appears as an inflatable and deflatable
19 on-demand balloon appliance in this preferred embodiment; a volumetric sheath 50; and
20 sheath position holding means which appear in this preferred embodiment as the grasping
21 member 70. The introducer assembly exemplified by Fig. 1 is in completely assembled
22 form; comprises each of the requisite and optional component parts and sub-assemblies in

1 its appropriate placement and position; and shows the entire optimized apparatus in a state
2 ready for immediate usage. Details of the individual component parts of the introducer
3 assembly are shown by Figs. 2-8 respectively.

4 Fig. 2 shows the minimal introducer assembly in detail which comprises only the
5 perforator instrument 10 and the balloon appliance 40 which serves as one specific means
6 for controlling and deploying a prepared communication channel. As illustrated by Figs.
7 2A and 2B, the perforator instrument 10 of the minimalist introducer assembly is
8 comprised of at least one elongated supporting shaft 12 of predetermined overall
9 dimensions and axial length having two ends 14, 16; and has a internal lumen 18. Knob
10 handle 15 is attached at the end 16 of the supporting shaft 12; and a perforating headpiece
11 30 is joined to the supporting shaft at the other shaft end 14. The perforating headpiece 30
12 is integrally joined to the end 14 of the supporting shaft 12 and itself comprises a
13 perforating tip 32, a penetrating body 34, and a base aspect 36.

14 The perforator instrument 10 is thus itself an assembly of parts which provides a
15 knob handle for the surgeon and a cutting headpiece suitable for penetrating the sidewall
16 tissue of a blood vessel or hollow organ and forming an aperture in-situ.

17 Disposed adjacent to the perforating headpiece 30 on the supporting shaft 12 of the
18 perforator instrument 10 is an inflatable and deflatable on-demand balloon appliance 40. In
19 this minimalist format and first preferred embodiment, the balloon appliance 40 structurally
20 serves as communication channel controlling means for the deployment of the introducer

1 assembly as a whole; and provides the primary apparatus for controlling the positioning of
2 a previously prepared communication channel which, after proper placement within the
3 assembly, will serve either as a vascular bypass graft or an access duct in-vivo.

4 The balloon appliance 40 -- the communication channel controlling means in this
5 embodiment -- is comprised of an expandable and deflatable balloon 42 whose interior
6 volumetric space can be increased and decreased on demand repeatedly without difficulty;
7 an inflation line 44 joined to the interior space of the balloon 42; and a luer lock fitting 48
8 joined to the inflation line 44 but positioned adjacent to the knob handle 15. The luer lock
9 fitting 48 provides the direct communication means for introducing a inflation fluid from an
10 external source (not shown) into the inflation line 44 through which the inflation fluid will
11 be carried and transported into the interior volumetric space of the balloon 42. By adding
12 fluid through or allowing fluid to flow out of the luer lock fitting 48, the degree of inflation
13 or deflation for the balloon appliance 40 can be controlled and maintained at will.

14 The volumetric sheath 50, an optional but highly desirable structure of the
15 introducer assembly, is illustrated by Figs. 3A and 3B respectively. The optional
16 volumetric sheath 50 has two open ends 52, 54 and at least one sidewall 56 of
17 predetermined dimensions. The volumetric sheath 50 is sized at the open end 52 for on-
18 demand placement adjacent to and aligned closure with the perforating headpiece 30 of the
19 perforator instrument 10. In addition, the optional volumetric sheath 50 is substantially
20 annular in configuration over its axial length but is desirably constricted at the open end 52
21 to conform to the particular dimensions of the perforating headpiece 30. The essential
22 purpose and function of the volumetric sheath 50 is protection such that its internal spatial

1 volume 58 over its axial length becomes available and adapted for protective positioning
2 around and volumetric spatial envelopment of at least a portion of the supporting shaft 12
3 which extends from the perforating headpiece 30 of the perforator instrument 10.

4 As shown in Fig. 1 previously, the optional volumetric sheath 50 when properly
5 positioned provides a protective covering and envelope for the spatial volume and ambient
6 environment then surrounding the supporting shaft 12; and any contents (including a
7 prepared communication channel which is then positioned within the internal spatial
8 volume 58 of the volumetric sheath 50) will become protectively surrounded and enveloped
9 by the sheath sidewall 56 over the entirety of the axial length for the configured volumetric
10 sheath 50. For the introducer assembly as a whole, particularly as depicted by Fig. 1, the
11 volumetric sheath 50 provides the protective envelopment of an ambient environment
12 spatial volume and all its interior contents which then surround the supporting shaft 12 and
13 the introducer assembly as an integrated unit.

14 The optional position holding means 70 and its intended function within the
15 preferred introducer assembly is illustrated by Figs. 4 and 5 respectively. Figs. 4A and 4B
16 each illustrate the grasping member 70 which is the specific embodiment of the optional
17 position holding means in this assembly; while Fig. 5 shows the interrelationship between
18 the grasping member 70 and the volumetric sheath 50 as intended by the assembly of parts.

19 As shown by Figs. 4A and 4B, the grasping member 70 comprises a grip 72; a shaft
20 mounting 74 configured for disposition around the support shaft 12 of the perforator
21 instrument 10; and a sheath positional end fitting 76 which is annular or circular in overall
22 configuration and dimensioned to fit snugly in a friction holding position with the open end

1 54 of the volumetric sheath 50. It will be noted and appreciated also that the shaft
2 mounting 74 is itself substantially circular in configuration and is comprised of a flange 75
3 and a encircled aperture 77 through which the supporting shaft 12 will pass axially.

4 When properly aligned with the optional volumetric sheath 50, the overall result is
5 illustrated by Fig. 5. Clearly, the open ends 52, 54 of the volumetric sheath 50 are in
6 alignment with the grasping member 70; and the entire internal spatial volume 58 of the
7 volumetric sheath 50 is encompassed by the attachment of the position holding grasping
8 member 70 at the end 54. The grasping member thus provides position holding means and
9 maintenance for the volumetric sheath within the introducer assembly over most of its axial
10 length.

11 The arrangement of each of the requisite and optional component parts illustrated by
12 Figs. 2-5 is thus shown properly aligned and assembled as a preferred structural apparatus
13 by Fig. 1. As the grasping member 70 is advanced forward or pulled rearward over the
14 supporting shaft 12 of the perforating instrument 10, the volumetric sheath 50 will
15 concomitantly be advanced forward or pulled rearward as a consequence. Thus, at any
16 moment or instance of use, the volumetric sheath 50 as a whole and its internal spatial
17 volume 58 as well as any contents to be found within the internal spatial volume itself can
18 be advanced to and beyond the perforating headpiece 30 or pulled rearward to reveal the
19 component parts of the perforator instrument. In this manner the perforating headpiece 30
20 can be alternatively and repeatedly exposed or hidden within the internal spatial volume 58
21 of the volumetric sheath 50.

22

1 The purpose and function of the introducer assembly is to provide for a catheterless
2 and sutureless juncture of a prepared communication channel to the interior of a blood
3 vessel or a hollow organ in-vivo. For descriptive purposes, the prepared communication
4 channel is briefly illustrated by Figs. 6A, 6B, and 6C which show the proper parts of a
5 prepared communicating channel to be used within the introducer assembly. The essential
6 parts are briefly illustrated by Fig. 6; but a far more detailed description of the major forms
7 and alternative embodiments of communicating channels as a manufactured article are
8 subsequently disclosed herein as well as illustrated by Figs. 34-47 inclusive.

9 As shown by Fig. 6, a prepared communication channel 80 is comprised of a
10 linking connector 82 and a tubular conduit 90. The tubular conduit 90 is any tube or
11 hollow channel having two open discrete ends 92, 94; at least one tubular sidewall 96; and
12 an internal lumen 98 of fixed spatial volume. The tubular conduit 90 accordingly also has
13 an internal sidewall surface 95 which is co-extensive with the internal lumen 98; and an
14 external sidewall surface 97 of predetermined dimensions and overall configuration.
15 Further details regarding the tubular conduit 90 are described hereinafter.

16 The linking connector 82 is shown as an open wire meshwork construction in Figs.
17 6B and 6C respectively. The linking connector includes at least a first cuff portion 84 of
18 predetermined dimensions and configuration which is superelastic and/or thermo-elastic,
19 thermo-plastic and deployable on-demand. The first cuff portion 84 is configured for
20 passage through an aperture in the wall of a blood vessel or a hollow organ; is superelastic;
21 and is deformable and deployable on-demand whereby the act of deformation in-situ within
22 the interior volumetric space of a blood vessel or hollow organ serves to secure the joined

1 tubular conduit interior of the blood vessel or hollow organ and places the secured tubular
2 conduit in fluid flow communication with the interior volumetric space of the blood vessel
3 or hollow organ proper. The linking connector also includes a second conduit retaining
4 portion 86 of determined dimensions and configuration which is joined to the sidewall 96
5 of the tubular conduit 90 such that the joining retains and secures the tubular conduit 90 for
6 fluid flow communication purposes.

7 The juncture of the linking connector 82 may be made either at the external sidewall
8 surface 97 as shown in Fig. 6B or alternatively at the internal sidewall surface 95 as
9 illustrated by Fig. 6C. In many instances the juncture of the second conduit retaining
10 portion 86 is desirably done within the internal lumen 98 by direct joining to the internal
11 sidewall surface 95. However, any format of juncture [using staples, sutures or any other
12 permanent means for joining] is suitable for use within the introducer assembly.

13 Accordingly, the prepared communication channel 80 as a prepared article of manufacture
14 is shown equally by Figs. 6B or 6C without distinction or meaningful difference.

15 For purposes of further description the communication channel 80 will be prepared
16 in the manner illustrated by Fig. 6C where the linking connector 82 is joined along its
17 retaining portion 86 to the internal sidewall surface 95 of the tubular conduit 90. The
18 placement of the prepared communication channel as embodied by Fig. 6C is shown in Fig.
19 7.

20 As illustrated by Fig. 7, the prepared communication channel 80 is intended to be
21 positioned over perforator instrument 10. This positioning is accomplished by inserting the
22 perforating headpiece 30 and the supporting shaft 12 of the perforator instrument 10 into

1 the internal lumen 98 of the tubular conduit 90 via the open end 94. The perforating
2 headpiece 30 is then extended through the internal lumen 98 until it exits the
3 communication channel 80 at the other tubular conduit end, thereby concomitantly also
4 passing through the joined linking connector 82 in its entirety. Supporting shaft 12 will
5 then hold and support the entirety of the prepared communication channel 80 in this
6 position within the introducer assembly; and the volumetric sheath with grasping member
7 70 is subsequently placed around prepared communication channel 80. This results in the
8 completely arranged introducer assembly illustrated by Fig. 8.

9 As seen therein, Fig. 8A shows a perspective view of the complete introducer
10 assembly with the prepared communication channel 80 contained within the internal spatial
11 volume 58 of the volumetric sheath 50. To illustrate better the aligned positioning within
12 the introducer assembly, a cross sectional view along the axis AA' of Fig. 8A is provided
13 and shown in detail via Fig. 8B. As seen therein, the prepared communication channel 80
14 is housed within the internal spatial volume 58 of the volumetric sheath 50; is completely
15 enveloped by the volumetric sheath 50; and is protected by the covering of the volumetric
16 sheath 50 while supported on the supporting shaft 12 of the perforator instrument 10. The
17 first cuff portion 84 has been placed adjacent the penetrating body 34 of the perforating
18 headpiece 30 while the second conduit retaining portion 86 joined to the internal sidewall
19 surface 95 of the tubular conduit 90 appears positioned around the balloon appliance 40.
20 As noted previously, the balloon appliance may be inflated and deflated at will; and by
21 inflating the balloon appliance 40 in this setting, the inflated balloon will thus hold the
22 entirety of the prepared communication channel 80 firmly and indefinitely and prevent the

1 channel from moving linearly until such time that the balloon 40 is deflated again. Equally
2 important, the entirety of the perforator instrument 10 including the perforating headpiece
3 30 may be advanced forward or pulled rearward at will at any time while positioned within
4 the internal lumen 98 of the tubular conduit 90 and the joined linking connector 82. In
5 this manner, the entire axial length of the perforator instrument may be advanced or
6 withdrawn while the prepared communication channel 80 remains in a single position
7 within the enveloped spatial volume 58 provided by the protective volumetric sheath 50.

8 The complete introducer assembly illustrated by Fig. 8 is shown in the intended
9 application and usage for the introduction and sutureless juncture of a prepared
10 communication channel by Figs. 9-14 respectively. These figures 9-14 inclusive illustrate
11 that the anatomic body part penetrated is typically a blood vessel or a hollow organ 100.
12 The targeted body part 100 has at least two walls 102, 104 and an internal spatial organ
13 volume 108. This is illustrated in its generic form within Figs. 9-14.

14 Fig. 9 shows the complete introducer assembly as it approaches the front sidewall
15 102 of the blood vessel or hollow organ. It will be seen therein that the open end 52 of the
16 volumetric sheath is placed adjacent to and in aligned closure with the perforating
17 headpiece 30 of the perforator instrument. The prepared communication conduit 80 lies
18 entirely within the internal spatial volume 58 of the volumetric sheath 50 as does the
19 balloon appliance 40 and the supporting shaft 12 of the perforator instrument. Also, as
20 shown by Fig. 10, the balloon appliance is in the deflated state thereby permitting the
21 entirety of the perforator instrument 10 and the penetrating tip 32 in particular to pass out
22 of the enveloped spatial volume provided by the volumetric sheath 50; then to cut into the

1 sidewall 102; and thereby form an aperture 110. The introducer assembly as a whole is
2 then advanced forward through the newly formed aperture 110.

3 Fig. 10 also shows the position of the prepared communication channel as an
4 integrated unit through the aperture 110 in the front wall 102 of the blood vessel or hollow
5 organ. As seen therein, the volumetric sheath 50 housing the linking connector 82 has
6 been pushed forward such that the first cuff portion 84 lies positioned within the internal
7 spatial volume of the blood vessel or hollow organ 100; and the perforating headpiece 30
8 and the deflated balloon appliance 40 have also been extended into the internal spatial
9 volume 108 and thus support the prepared communication channel in this position.

10 The balloon appliance then is preferably inflated by introducing fluid via the luer
11 lock fitting (not shown) which is passed through the inflation line and inflates the balloon
12 interior space 42 thereby holding the prepared communication channel 80 in place within
13 the aperture 110 itself. This is illustrated by Fig. 11.

14 Accordingly, the linking connector 82 which has been permanently joined to the
15 internal sidewall surface 95 of the tubular conduit 90, is then allowed to deform on-demand
16 and deploy in-situ. This event is shown by Fig. 12. The individual acts of deformation
17 and deployment of the first cuff portion 84 within the internal spatial volume 108 of the
18 blood vessel or hollow organ 100 thus serve to secure the prepared communication channel
19 80 to the interior of the anatomic body part; and concurrently places the secured
20 communication channel 80 in fluid flow communication with the internal spatial volume
21 108 of the blood vessel or hollow organ. Moreover, while the act of deployment within the
22 internal spatial volume 108 occurs as illustrated by Fig. 12, the tubular conduit

1 permanently joined to the second conduit retaining portion 86 remains in place and in a
2 somewhat expanded state by superelasticity, thermoelasticity, and/or balloon inflation.
3 This retained portion 86 permanently joined to the sidewall of the tubular conduit retains
4 and secures the tubular conduit 90 for unobstructed fluid flow communication.

5 The final stages of the method and system are illustrated by Figs. 13 and 14
6 respectively. Fig. 13 shows the introducer assembly being withdrawn after deflation of the
7 balloon from within the internal lumen 98 of the tubular conduit 90. Fig. 14 illustrates the
8 final desired result and shows the sutureless juncture of the prepared communication
9 channel 80 in position through the aperture 110 in the front wall 102 of the blood vessel or
10 hollow organ 100. As seen therein, the prepared communication channel is joined to the
11 interior space of the blood vessel or hollow organ; is secured in a fluid-tight manner to the
12 internal spatial volume 108 of the blood vessel or hollow organ interior; and is in fluid
13 flow communication with the interior space of this anatomic body part. The linking
14 connector 82 shows the first cuff portion 84 in the deformed state within the interior space
15 of the blood vessel or hollow organ and shows that this in-situ deformation acts to secure
16 the tubular conduit 90 to the interior spatial volume of the blood vessel or hollow organ
17 and places the prepared communication channel in fluid flow communication for whatever
18 purpose is desired by the surgeon for his patient.

19

20 II. Alternative Embodiments And Formats

21 The first preferred embodiment described previously herein is merely one structural
22 assembly format whose component parts may be alternatively configured for a variety of

1 purposes. To demonstrate the variety of alternative embodiments and structural formats,
2 the following structural designs and constructions are provided. It will be expressly
3 understood, however, that these described alternative embodiments and constructions are
4 merely illustrative of the wide range and broad variety of alternatives which is well within
5 the skill of the ordinary person skilled in this technical field; and that the described formats
6 are merely representative examples of many other constructions which may be used equally
7 well for a particular medical application or specific patient purpose.

8

9 Alternative embodiment 1:

10 A first alternative design and construction facilitates the passage and removal of the
11 prepared communication channel over the axial length of the perforator instrument and
12 concurrently allows for easy removal of the perforator instrument as well as the introducer
13 assembly as a whole after the communication channel has been joined in-situ to the interior
14 spatial volume of a blood vessel or hollow organ. For this purpose a first alternative
15 construction for the perforating headpiece of the perforator instrument is provided as
16 illustrated by Fig. 15. As seen therein, the perforating headpiece 130 now comprises a
17 perforating cutting tip 132, a penetrating body 134 of diminished dimensions and size in
18 comparison to that described previously herein; has a base aspect 136 which is now serving
19 as a surface for a cone-shaped end element 138. As before, the perforating headpiece 130
20 is integrally joined to the supporting shaft 12 of the perforator instrument. In this
21 construction, the point of juncture and integral union for the perforating headpiece 130 as a
22 unit is at the cone-shaped end element 138.

1 The benefit and major advantage of this construction is that the cone-shaped base
2 end element 138 is tapered along its sides 140; and that this tapered sidewall 140 for the
3 cone-shaped end element 138 will not only permit easier passage and withdrawal through
4 the linking connector; but also, if necessary, dilate the linking connector structure to permit
5 an unobstructed withdrawal of the perforating headpiece 130 after the communication
6 channel has been joined to the blood vessel or hollow organ interior space. If desired, the
7 entire external surface of the perforating headpiece and the sides 140 of the cone-shaped
8 base end element 138 in particular may be covered with a hydrophilic coating in order to
9 provide a more slippery surface and ensure an easier passage.

10

11 Alternative embodiment 2:

12 This second alternative embodiment and structural construction is illustrated by
13 Figs. 16-19 respectively. There are two essential parts to this second alternative
14 embodiment. The first is revealed by Figs. 16, 17A, and 17B respectively which
15 reproduce in part the perforating headpiece 130 illustrated by Fig. 15 and described herein
16 previously. In this alternative construction, the perforating headpiece 130 again includes a
17 perforating tip 132, a penetrating body 134, a base aspect 136, and a cone-shaped end
18 element 138; but also now comprises a plurality of recesses which individually appear as a
19 groove 165 and a furrow 167 within the penetrating body portion 134 and the base aspect
20 136 respectively.

21 Particular details of this structural construction are shown by Figs. 17A and 17B
22 respectively. As seen therein the recessed groove 165 is circumferentially extensive and

1 deep within the penetrating body 134. Similarly, the recessed furrow 167 circumferentially
2 penetrates sharply through the base aspect 136 and the interior of the penetrating body 134.
3 The cross sectional view illustrated by Fig. 17A shows the manner in which the recessed
4 groove 165 and recessed furrow 167 exist in depth; in comparison, the cross-sectional
5 view of the perforating headpiece 130 (looking forward from the supporting shaft towards
6 the perforating tip 132) of Fig. 17B shows the concentric ring nature and annular alignment
7 of the recessed groove 165 in comparison to the recessed furrow 167.

8 This second alternative embodiment of the perforating headpiece 130 having
9 recessed groove 165 and recessed furrow 167 is intended to be employed with a modified
10 construction for the volumetric sheath illustrated by Fig. 18. In this modified design
11 structure and construction, the volumetric sheath 150 has a front open end 152 which is
12 configured as multiple segmented tangs 154. The multiple segmented tangs 154 are
13 preferably evenly spaced around the circumference of the open end 152 and are desirably
14 biased such that the preferred positioning of the segmented tangs is in the open position as
15 shown in Fig. 18. The multiple biased segmented tangs 154 when compressed annularly
16 into the closed position will form a single circular and unified open end 152; and while in
17 the closed position will provide a unitary opening 152 for the entirety of the volumetric
18 sheath 150 despite being constructed as multiple segmented pieces. In this manner, the
19 segmented tangs 154 will remain preferably in the open, biased position; but at will can be
20 compressed to form a single circular or annular front end opening 152 and access to the
21 interior spatial volume of the volumetric sheath 150.

22

1 The positioning of the multiple segmented tangs 154 in the closed position is
2 intended for placement within the recessed groove 165 of the perforating headpiece 130
3 illustrated previously in Figs. 16 and 17 respectively. The segmented tangs 154 will fit
4 into and be held by the recessed groove 165; and form itself within the interior space of the
5 groove as the unitary annular opening 152. This is shown by Fig. 19. In addition, the
6 recessed furrow 167 will receive and hold the first cuff portion 84 of the linking connector
7 82 after it has been permanently joined to the tubular conduit as the prepared
8 communication channel. The placement of the linking connector 82 at the first cuff portion
9 84 into the recessed furrow 167 is also illustrated in Fig. 19. This linking connector
10 placement thus allows a further degree of certainty and safety for the prepared
11 communication channel after it has been positioned around the supporting shaft of the
12 perforator instrument and has been enveloped by the volumetric sheath 150.

13

14 Alternative Embodiment 3:

15 A third alternative construction provides a variant format for the volumetric sheath
16 of the introducer assembly. This third alternative construction is illustrated by Fig. 20 and
17 utilizes in part the volumetric sheath structure illustrated by Fig. 18 and described in detail
18 previously herein. In this alternative embodiment, however, the variant structure includes
19 inner sleeve 160 which is of predetermined dimensions and substantially cylindrical
20 configuration. The inner sleeve 160 comprises a open front end 162, an open rear end
21 164, and a cylindrically-shaped grip 161 joined to the rear end 164. Not only does the
22 inner sleeve 160 slide forward and rearward at will within the interior volume of the

1 volumetric sheath 150; but as the inner sleeve 160 is slid forward towards the segmented
2 tangs 154, the front end 162 engages the segmented tangs 154 of the volumetric sheath 150
3 and forces the tangs open as a consequence of the physical engagement. This allows quick
4 and easy removal of the volumetric sheath 150 from the introducer assembly, especially
5 after the segmented tangs 154 have been placed in the closed position forming a unitary
6 annular front end.

7 One major benefit and advantage of this alternative construction using the inner
8 sleeve 160 as illustrated within Fig. 20 is that this format allows the volumetric sheath 150,
9 the outer sheath covering, to be made of a woven synthetic textile material which is
10 prepared in advance and coated with a non-porous polymer coating. The polymer coating
11 would preferably bias the woven textile material of the outer volumetric sheath in the
12 closed position in which the multiple segmented tangs would reform as a single annular
13 opening. Thus, as the inner sleeve is advanced within the outer volumetric sheath, it would
14 effectively expand the polymer coated woven textile material and permit removal of the
15 outer volumetric sheath in a far easier fashion.

16 Clearly this type of construction and format allows for a volumetric sheath which is
17 composed or designed using a woven synthetic textile material; and thus allows a fabric
18 type construction and a fabric arrangement for the outer sheath which acts as the protective
19 barrier and covering around the perforating instrument. This type of woven textile
20 construction and embodiment for the volumetric sheath, with or without the presence and

1 use of an inner sleeve as shown within Fig. 20, is merely one variant of the many different
2 constructions and materials which may be employed with the introducer assembly as a
3 whole.

4

5 Alternative embodiment 4:

6 A fourth alternative design and construction is illustrated by Figs. 21 and 22
7 respectively. This format and structural design permits the surgeon to utilize the Seldinger
8 technique, a favored procedure for this kind of surgery. In this technique, a guidewire is
9 positioned in the targeted blood vessel or hollow organ wall; and it is this guidewire which
10 is then utilized as the means for precise guidance and placement of the introducer assembly
11 as a whole at that precise anatomic location. For this purpose the alternative construction
12 of Figs. 21 and 22 is added to the first preferred embodiment previously described herein.

13 As illustrated, the perforator instrument is comprised of the supporting shaft 12, the
14 perforating headpiece 30 and the knob handle 15. However, within the internal lumen 18
15 of the support shaft 12, a second hollow lumen 180 exists which extends and passes
16 through the axial length of the perforator instrument 10. This is shown by Fig. 21. The
17 guidewire hollow lumen 180 extends through the perforating headpiece 30, through the
18 supporting shaft 12 over its axial length, and exits adjacent to the handle 15 where it is
19 joined to flexible tubing 182. The flexible tube 182 is joined to the hollow lumen 180 at
20 the juncture point 186; and the flexible tube 182 provides an entry portal 184 through
21 which the guidewire exits. A cross sectional view of this internal arrangement, the
22 perforating headpiece end, is illustrated by Fig. 22.

The use of the Seldinger technique and the ability to pass a guidewire from the anatomic targeted site at the blood vessel wall or hollow organ wall directly through the perforating tip of the perforating headpiece and continuously through the entirety of the introducer assembly provides a major advantage and benefit for the assembly.

III. A Second Preferred Embodiment

A second preferred embodiment of the introducer assembly and system which is the present invention is illustrated by Figs. 23 through 33 respectively. This second preferred embodiment conforms to and satisfies the minimal component part requirements of each and every introducer assembly as a whole; but this preferred embodiment is a far more elaborate and sophisticated engineering design and construction.

An overview of this second preferred embodiment is provided by Fig. 23 which shows the introducer assembly 202 as an arranged apparatus comprising a perforator instrument 210, volumetric sheath 250, and position holding means configured as a pistol-grip mounting 204.

A detailed view of the perforator instrument 210 and the means for controlling the communication channel configured as a cuff stopper/holder subassembly 270 are shown by Figs. 24, 25, 26, and 27 respectively. As seen therein, the perforator instrument 210 is comprised of two coaxial support shafts 212 and 222. The longer and innermost support shaft 212 has two ends 214, 216 and an internal lumen 218. A knob handle 215 is joined to the support shaft 212 at the end 216. At the other shaft end 214 is attached to a perforating headpiece 230.

1 The second coaxial support shaft 222 is somewhat larger in overall diameter over its
2 axial length than counterpart support shaft 212. This second support shaft 222 has two
3 ends 224, 226; and a control knob 225 joined to the shaft 222 at the end 226. When
4 coaxially joined together the support shaft 222 serves as the external or outermost shaft
5 whereas the innermost support shaft 212 lies internally and coaxially within its diameter.
6 This relationship is illustrated by Figs. 26 and 24 respectively.

7 The perforating headpiece 230 is seen in detail within Fig. 26 and is comprised of a
8 multi-faceted cutting tip 232, a penetrating body 234, a base aspect 236, a recessed furrow
9 267, and a cone-shaped base end element 238. The cone-shaped base end element is
10 collapsible to accommodate the positioning of the cuff into the cone-shaped base element
11 and expandable to accommodate the withdrawal of the headpiece through the deployed cuff.
12 This perforating headpiece 230 is integrally joined to the supporting shaft 212 at the front
13 shaft end 214.

14 One advantage of the perforating headpiece 230 is the multi-faceted cutting tip 232
15 which provides multiple faces and cutting edges 232. The number of multiple faces and
16 edges is typically from 3-5 edges; and such a multi-faced and multi-edged bladed tip is
17 deemed to be more effective as a cutting tool than a single bladed tip. In addition, it is
18 recognized that single bladed or edged perforating tips often produce lacerations in the
19 blood vessel or hollow organ wall which subsequently may fracture or fragment. For this
20 reason it is believed that multi-faced and multi-edged cutting tips are preferred and would
21 be ideal in most use applications.

22

1 The communication channel controlling means is specifically embodied as connector
2 stopper/holder subassembly 270 and is best illustrated by Figs. 26, 28A, and 28B. As seen
3 therein, the collapsed position for the stopper/holder 270 is illustrated by Fig. 28A while
4 the open or expanded position is illustrated by Fig. 28B. As seen therein, the stopper
5 subassembly 270 comprises expandable and collapsible segments 274, each of which is
6 mounted on a segment supporting strip 276. The stopper subassembly 270 is joined to
7 coaxial supporting shaft via the support strips 276; and passes coaxially over the inner
8 supporting shaft 212 over its axial length within the internal lumen 301 of the outer
9 supporting shaft 300. When the outer supporting shaft 300 is withdrawn rearward, the
10 stopper 270 expands into its open position as shown; and when outer supporting shaft 300
11 is advanced forward over the supporting strips 276, the stopper segments 274 are pulled
12 together forcing the stopper subassembly into the collapsed state as shown by Fig. 28.

13 The purpose of the stopper/holder subassembly 270 is to provide a structural
14 backstop for the linking connector (then already joined to the tubular conduit as the
15 prepared communication channel); and to support the back of the linking connector during
16 withdrawal of the perforating headpiece 230. The stopper/holder assembly 270 is
17 expanded during placement of the linking connector; and the expanded stopper subassembly
18 engages the end of the linking connector as a back stop. When properly, the linking
19 connector (already joined to the tubular conduit) will thus rest against the front face 280 of
20 the stopper subassembly; and the stopper subassembly thereby provides the means for
21 controlling the prepared communication conduit while positioned within the introducer
22 assembly. Once the prepared communication conduit is deployed into the interior space of

1 a blood vessel or hollow organ target, the stopper/holder subassembly 270 is reduced into
2 the collapsed state and allows the subassembly to be withdrawn rearward as part of the
3 perforator instrument 210.

4 The volumetric sheath 250 of the second preferred embodiment is shown in detail
5 by Fig. 27. As seen therein, the volumetric sheath 250 comprises two open ends 252, 254;
6 a sidewall 256; and an internal spatial volume 258. In this embodiment for the volumetric
7 sheath 250, a flange 260 is mounted on the exterior surface of the volumetric sheath at the
8 open end 252. This end flange 260 has an extended annular rib 262 and a rib perimeter
9 264 of predetermined dimensions. At the other open end 254 is a sidewall alignment hole
10 266 which is utilized in the positioning of the volumetric sheath 250 within the introducer
11 assembly by acting to stop the forward motion of the introducer assembly and to limit entry
12 of the assembly to only that degree which is needed.

13 Finally, the position holding means which are attachable to and detachable from the
14 volumetric sheath of Fig. 27, and used for holding the volumetric sheath 250 and its
15 enveloped spatial volume at a set position around the two supporting shafts 300, 212, 222,
16 is best seen in Fig. 23. As illustrated therein, the position holding means is embodied as a
17 pistol-grip mounting 204 having a mounted body 206 and a finger grip 208. The
18 volumetric sheath 250 is internalized at the end 254 and held in aligned position via the
19 sidewall alignment hole 266; and the pistol-grip mounting holds the volumetric sheath via
20 the alignment hole 266 in the complete introducer assembly.

21 One additional feature is provided as an extra point of manipulation and control for
22 the introducer assembly as a whole. This is shown as the knob 285 and appears in Figs. 23

1 and 28 to best advantage. The controller knob 285 is mounted on the exterior surface of
2 the outermost support shaft 300. In aligned position, the control knob 285 is located within
3 the pistol-grip mounting 204; allows for manipulation of the outer most supporting shaft
4 300; and is a controller for placing the stopper subassembly 270 from an open position into
5 a collapsed position and subsequently back into an open position repeatedly on-demand.
6 This is an optional feature but a preferred item in this embodiment because it provides
7 precision control for the connector stopper subassembly without major change in position
8 of either coaxial supporting shaft 212 and 222 respectively.

9 When a prepared communication channel 80 is positioned within this introducer
10 assembly 250, the complete system methodology is ready to be used by the surgeon. A
11 cross sectional detail of the complete introducer assembly is provided by Fig. 29. As seen
12 therein, the communication channel 80 is positioned within the internal spatial volume 258
13 of the volumetric sheath 250. Placed within the internal lumen 98 of the tubular conduit 90
14 is the perforator instrument 210 including the perforating headpiece 230, the inner
15 supporting shaft 222, the stopper subassembly 270 in the expanded state, and the outer
16 supporting shaft 300. By use of the stopper subassembly 270 which is positioned against
17 the second retained portion 86 of the linking connector 82, full manipulative control of the
18 communication channel as a prepared article of manufacture is maintained throughout.

19 The deployment and method of usage for this second preferred embodiment is
20 shown by Figs. 30-33 respectively. The complete introducer assembly illustrated within
21 Fig. 29 and generally by Fig. 23 is employed as shown to penetrate the wall of a targeted
22 blood vessel or hollow organ. This is shown by Fig. 30. The perforating headpiece 230

1 has penetrated into the interior spatial volume of the targeted blood vessel or organ while
2 the end flange 260 of the volumetric sheath 250 remains against the exterior surface of the
3 target. The end flange 260 serves to stop the forward motion of the introducer assembly as
4 a whole by providing a larger diameter sheath than the aperture formed by the perforating
5 headpiece 230. After the perforation aperture has been made, the perforating headpiece
6 230 alone is advanced forward thereby releasing the first cuff portion 84 from the recessed
7 furrow 267. The linking connector is now free to deform in full and to be deployed
8 completely in-situ within the internal spatial volume of the penetrated target vessel or
9 organ. This is illustrated by Fig. 31.

10 Subsequently, the perforating headpiece 230 may be withdrawn through the internal
11 lumen of the joined and secured communicating channel. This is illustrated by Fig. 32 and
12 is achieved by manipulating the controlling knobs 215 and 225 rearward. The knob 285 is
13 then advanced to collapse the stopper subassembly. The entire introducer assembly is then
14 pulled back using the finger grip 208 of the pistol-grip mounting 204, the deformed linking
15 connector and tubular conduit joined and secured to the internal spatial volume of the
16 targeted blood vessel or hollow organ. This result is illustrated by Fig. 33.

17

18 IV. The Prepared Communication Channel

19 A. The Linking Connector

20 An essential component part of the prepared communicating channel is the presence
21 and use of a superelastic and thermoelastic linking connector preferably comprised of a
22 shape-memory alloy composition.

1 The shape-memory metal alloy compositions preferably used with the present
2 invention constitute conventionally known blends and formulated metallic mixtures of
3 nickel and titanium which undergo a phase transition--that is, a molecular rearrangement of
4 atoms, molecules or ions within a lattice structure--due to a temperature change. The
5 unique capability of shape-memory alloys is that these alloys are extremely elastic, flexible,
6 and durable; these alloys change shape or configuration as a direct consequence of a change
7 in temperature; and the alloy composition "remembers" its earlier and specifically prepared
8 shape because the phase change affects its structure on the atomic level only, without
9 disturbing the arrangement of the molecules which would otherwise be irreversible.

10

11 Superelasticity and thermoelasticity

12 When these shape-memory alloys are intentionally superheated far above their
13 transition temperature (either electrically or by external heat), a stretched temperature
14 transformed alloy format results which contracts and exerts considerable force; and the
15 temperature transformed alloy composition will become memory-shaped (deformable in-
16 situ) in a fixed specific configuration. Afterwards, when cooled to below its transition
17 temperature, the prepared alloy composition presents superelasticity properties which allow
18 the alloy to be bent and shaped into other configurations while retaining the fixed
19 "memory" of the particular shape in the earlier superheated condition, the thermoelastic
20 properties. Thus, these shape-memory alloy compositions are recognized as being both
21 superelastic and thermoelastic compositions of matter.

22

1 Alloy formulations

2 At least twenty different formulations of these superelastic and thermoelastic alloys
3 are conventionally known, all of these comprising different mixtures of nickel and titanium
4 in varying percentage ratios [Design News, June 21, 1993 issue, pages 73-76]. These
5 metal alloys are conventionally utilized today in the manufacture of diverse products. For
6 example, a range of different shape-memory alloy wires are commercially available in
7 diameters from 0.001-0.010 inches [Dynalloy, Inc., Irvine, California]. In addition,
8 surgical anchors having such superelastic properties and formed by two or more arcs of
9 wire strands (which can withstand strains exceeding 10%) have been developed [Mitek
10 Surgical Products, Inc., Norwood, Massachusetts]. Also, blood clot filters formed of
11 superelastic shape-memory alloy wires are commercially sold for implantation in large
12 blood vessels such as the vena cava [Nitinol Medical Technologies, Inc., Boston,
13 Massachusetts]. While these commercially available products illustrate the use of one or
14 more superelastic and thermoelastic properties as particular articles, a more general listing
15 of conventionally known properties and characteristics for shape-memory alloy
16 compositions is provided by Table 1 below.

17

18

Table 1:

Conventionally Known Properties of
Shape-Memory Alloys¹

Transformation Properties

Transformation Temperature	-200 to -110°C
Latent Heat Of Transformation	5.78 cal/g
Transformation Strain (for polycrystalline material)	
for a single cycle	8% maximum
for 10 ² cycles	6%
for 10 ⁵ cycles	4%
Hysteresis*	30 to 50°C

Physical Properties

Melting point	1300°C (2370°F)
Density	6.45 g/cm ³ (0.0233 lb/in ³)
Thermal Conductivity	
austenite	0.18 W/cm · °C (10.4 BTU/ft · hr · °F)
martensite	0.086 W/cm · °C (5.0 BTU/ft · °F)
Coefficient of Thermal Expansion	
austenite	11.9x10 ⁻⁶ /°C (6.11x10 ⁻⁶ /°F)
martensite	6.6x10 ⁻⁶ /°C (3.67x10 ⁻⁶ /°F)
Specific Heat	0.20 cal/g · °C (0.20 BTU/lb · °F)
Corrosion Performance**	excellent

Electrical Properties

Resistivity (ρ)	
[resistance = $\rho \cdot \text{length/cross-sectional area}$]	
austenite	~ 100 $\mu\Omega \cdot \text{cm}$ (~39.3 $\mu\Omega \cdot \text{in}$)
martensite	~ 80 $\mu\Omega \cdot \text{cm}$ (~31.5 $\mu\Omega \cdot \text{in}$)
Magnetic Permeability	< 1.002
Magnetic Susceptibility	3.0x10 ⁶ emu/g

Table 1 (continued)

Mechanical Properties	
Young's Modulus***	
austenite	~83 GPa (~12x10 ⁶ psi)
martensite	~28 to 41 GPa (~4x10 ⁶ to 6x10 ⁶ psi)
Yield Strength	
austenite	195 to 690 MPa (28 to 100 ksi)
martensite	70 to 140 MPa (10 to 20 ksi)
Ultimate Tensile Strength	
fully annealed	895 MPa (130 ksi)
work hardened	1900 MPa (275 ksi)
Poisson's Ratio	0.33
Elongation at Failure	
fully annealed	25 to 50%
work hardened	5 to 10%
Hot Workability	quite good
Cold Workability	difficult due to rapid work hardening
Machineability	difficult, abrasive techniques are preferred

* Values listed are for a full martensite to austenite transition. Hysteresis can be significantly reduced by partial transformation or ternary alloys.

** Similar to 300 series stainless steel or titanium.

*** Highly nonlinear with temperature

1 All the different specific formulations and metallic blends comprising nickel and
2 titanium which yield a deformable, thermoelastic, shape-memory alloy composition are
3 suitable for use when practicing the present methodology. All of these shape-memory
4 alloys rely on a crystal phase change from a higher temperature Austenite form to a lower
5 temperature Martensite form to accomplish the memory effect. The cubic Austenite phase
6 behaves much like ordinary metals as it deforms. In contrast, the complex crystal
7 Martensite form can be found by reversible movement of twin boundaries to change the
8 average "tilt" or strain in each segment of the alloy. The overall strain can be eliminated
9 by releasing the stress, by maintaining it if it is not thermally stable (the superelastic
10 effect), or by heating the alloy to change it back to Austenite form (shape-memory effect).

11 The crystal transformation of shape-memory alloy compositions is, by definition,
12 thermoelastic--i.e., it progresses in one direction on cooling below the transition
13 temperature and in the other direction upon heating above the transition temperature. The
14 amount of transformation change versus temperature, measured either as the percent of
15 Martensite form or the strain in a constantly stressed element, is a function of and can be
16 plotted against temperature (°C) directly; and the change from one phase (and identifiable
17 shape) to another typically occurs in a narrow temperature range (often 5-10°C).
18 Hysteresis takes place before the reverse transformation occurs.

19 The amount of strain accommodated due to the movement of twin boundaries,
20 differs in each metallic alloy blending system. In the nickel-titanium system for example,
21 up to 8% reversible tensile strain is available; however, to guarantee a long life use, the
22 strain is often limited to 4-5%.

1 The stress-strain behavior of shape-memory alloy compositions is employed to help
2 explain the shape-memory effect. For instance, Martensite is much easier to deform than
3 Austenite. Therefore, one can deform the alloy while cold with much less force than when
4 heated to change it back into Austenite form. As a result, the alloy converts thermal
5 energy to mechanical work at high forces.

6

7 Fixing the memory-shaped configuration in the metal alloy

8 To prepare and fix the particular (or desired) shape to be "remembered" when the
9 alloy undergoes a temperature phase transition, the alloy composition must be superheated
10 initially to about 500°C (or roughly 930°F) for an hour while held in the fixed shape and
11 position to be memorized. During the superheating process, the native alloy blend enters
12 what is called the Austenite phase -- a rigid lattice of nickel atoms surrounded by titanium
13 alloys. Then, as the alloy metal cools below its transition temperature (which will vary
14 with the percentage proportions of nickel and titanium), the alloy composition adopts the
15 Martensite phase, in which the nickel and titanium atoms assume a very different
16 arrangement--one that is very easy to bend and deform. Subsequently, when the deformed
17 metallic alloy is reheated to the chosen transition temperature range between
18 25-35°C, thermal motion causes the atoms to snap back into the Austenite phase, thereby
19 restoring the fixed memory-shaped configuration of the object [Invention & Technology,
20 Fall 1993, pages 18-23].

21 For purposes of practicing the present invention, it is most desirable that the shape-
22 memory alloy composition be prepared in a metallic blend and formulation such that the

1 temperature transition phase occurs at a temperature less than about 35°C; but greater than
2 about 25°C; and preferably be in the range from about 30-35°C. This preferred 30-35°C
3 transition phase temperature range is dictated by the demands of the human body which
4 maintains a normal temperature at about 37°C (98.6°F); and typically shows a normal
5 temperature range and variance of one or two degrees Celsius above and/or below this
6 normative temperature standard. It is for this reason that the broad temperature range be
7 about 25-35°C and the preferred temperature transition occur in the range of 30-35°C; but
8 that such transformation into the intended and fixed memory-shaped configuration occur at
9 least by a temperature of 35°C to insure a safety margin of medical usefulness.

10

11 B. Thermoelastic Properties Of The Linking Connector

12 The shaped connector configurations of the thermoelastic alloy composition at
13 temperatures less than about 25-35°C (a temperature below its transition temperature at
14 which the alloy exists in the Martensite phase) may take a broad variety of different
15 lengths, diverse dimensions, and disparate overall configuration. Merely exemplifying the
16 range and diversity of three-dimensional forms into which the alloy compositions can be
17 shaped into a linking connector structure at temperatures below 25°C are those illustrated
18 by Figs. 34-37 respectively. For purposes of practicing the present invention, Figs. 34-35
19 are considered more preferred embodiments and constructions of the shaped alloy
20 structures, while Figs. 36-37 respectively represent formats and fabrications of the
21 deformed in-situ alloy compositions in less frequently utilized shaped configurations.

22

1 Effect of temperatures less than and greater than 25-35°C

2 As illustrated and embodied by Figs. 34A and 34B, the deformable in-situ,
3 thermoelastic linking connector is a substantially cylindrical-shaped collar which is open at
4 each of its ends 302, 304. The linking connector 300 is hollow; is substantially round or
5 oval (in cross-sectional view); and has a determinable first configuration and dimensions
6 initially which are deformed at will into a second memory-shaped configuration when
7 placed at a temperature greater than about 25-35°C.

8 It is most desirable that the thermoelastic material constituting the sidewall 306 of
9 the connector 300 be prepared and shaped as a first-configuration along the axis AA' as
10 shown within Fig. 34A; and that the thermoelastic material constituting the sidewall 306 be
11 an open-weave pattern of a memory-shaped alloy rather than take form as a solid mass of
12 thermoelastic alloyed material. For this reason, the sidewall 306 illustrated within Fig.
13 34A appears in the first configuration as an open meshwork of wires 308 which are
14 intertwined to form a substantially hexagonal pattern. This open meshwork of wires 308
15 provides the desired resiliency, flexibility, and memory-shaped deformation capability
16 (particularly along the axis AA') such that the first or upper cuff portion of the sidewall
17 306 will become deformed and flared outwardly on-demand to yield the memory-shaped
18 second configuration constituting the flared-lip deformity 310 shown by Fig. 34B.

19 It will be recognized and appreciated that the deformed cuff portion shown by
20 Fig. 34B is merely the result of removing the cuff structure from a temperature less than
21 25-35°C and placing it into a temperature environment greater than about 35-35°C. Thus,
22 solely as a consequence of the change in temperature, the uppermost cuff portion 309 of the

1 open meshwork of wires 308 above the axis AA' has become deformed in-situ such that the
2 upper sidewall 309 adjacent to the open end 302 has expanded outwardly, flared, and
3 become bent into a curved lip configuration in the memory-shaped deformed state. Note
4 that Fig. 34B shows the upper deformation in the fully deployed state; while the open
5 meshwork of wires constituting the lower retaining portion 307 of the sidewall 306 at the
6 other open end 304 remains relatively stable and substantially unaltered in its original shape
7 and state. Alternatively, however, the lower retaining sidewall portion 307 can be made to
8 expand or diminish slightly so that it will annularly fit more tightly outside of or within the
9 conduit wall. The deformation in-situ thus is controlled thermally and the forces at the
10 upper curve sidewall portion from the AA' axis cause the outwardly extending, flared lip
11 result as the fully deployed state. Moreover, the resulting flared lip zone 310 retains
12 structural strength and resiliency as an open meshwork of superelastic wires despite having
13 been deformed in-situ and deployed in full. The ability of the first cuff portion to be
14 deformed and deployed in the manner illustrated by Figs. 34A and 34B respectively is an
15 attribute and characteristic of each embodiment and construction for the thermoelastic
16 linking connector.

17 The construction and design for the linking connector is an example of the
18 engineering principle that structural form at will follow intended function. As a component
19 part of the system apparatus and methodology for attaching a tubular conduit in-vivo, the
20 functions of the linking connector are twofold in nature: (1) the temperature-deformable
21 linking connector is intended to engage and become joined to either a synthetic duct
22 prosthesis or a previously excised vascular segment which will serve as the tubular conduit

1 in-vivo; and (2) the temperature-deformable linking connector is intended to be positioned
2 within the internal lumen of an unobstructed major blood vessel (such as the aorta) or
3 within a hollow organ cavity such that a first portion of the connector wall becomes
4 positioned and secured within the internal lumen (the blood flow channel) of the
5 unobstructed blood vessel or the interior of the hollow organ permanently in a fluid-tight
6 manner. Thus, as illustrated by the embodiments of Figs. 34A and 34B, the uppermost
7 cuff region 309 of the alloy comprising the linking connector will be deformed on-demand
8 merely by warming the article to a temperature greater than 25-35°C; and such deformation
9 when deployed into a flared outwardly bent form will become secured within the lumen of
10 the unobstructed artery or vein or the cavity of the hollow organ. Concomitantly, the
11 retained portion 307 will remain permanently joined in substantially unaltered form to the
12 tubular conduit.

13 Several attributes and characteristics are commonly to be shared among all
14 embodiments and constructions of the thermally deformable and deployable on-demand
15 linking connector. These include the following:

16 (a) Only a portion of the alloy material constituting the memory-shaped linking
17 connector need be thermally deformable and deployable on-demand. For convenience and
18 greater facility in achieving such temperature initiated deformation in the degree and at the
19 time desired, it is preferred that the alloy composition forming the linking connector be an
20 open weave or wire meshwork rather than a solid sheet alloy mass, which is considered to
21 be more difficult to deform in a thermally-controlled manner. There is, however, no
22 substantive restriction or limitation as such at any time or under any intended use

1 circumstances which necessitates an avoidance of a solid sheet of material, either as a
2 single alloy sheet or as a laminated plank of alloy material. Accordingly, the choice of
3 whether to use an open wire meshwork or a solid sheet of alloy material is left to the
4 discretion of the user.

5 (b) The thermoelastic linking connector need only be comprised of superelastic,
6 resilient and flexible metallic alloy matter. A number of different alloys of varying
7 formulations may be usefully employed when making a deformable memory-shaped linking
8 connector suitable for use with the present invention. Among the desirable alloy
9 formulations are those characterized by Table 1 above.

10 (c) After the deformable in-situ and deployable at will linking connector has been
11 manufactured using shape-memory alloy materials, the first configured cuff portion
12 structure (prior to thermal deformation) may be covered to advantage with one or more
13 biocompatible coatings. These biocompatible coatings are intended to water tighten the
14 article and to facilitate the sewing of the tubular conduit to the linking connector as well as
15 to reduce the interactions of the immune system and tissue reaction with the prepared
16 communicating channel after it has been secured in their appropriate locations in-vivo.
17 Such biocompatible coatings are conventionally known; will reduce the severity and
18 duration of immune or tissue reactions which frequently disrupt or interfere with grafts;
19 and are considered desirable in a majority of use instances in order to minimize the body
20 reaction to surgery. A representative listing of biocompatible coatings deemed suitable for
21 use with the deformable thermoelastic connector is provided by Table 2 below.

22

Table 2: Biocompatible Coatings

High temperature pyrrogen-free carbon;
Polytetrafluoroethylene (PTFE) and other polyhalogenated carbons;
Fibronectin;
Collagen;
Hydroxyethyl methacrylates (HEMA);
Serum albumins;
Suprafilm (Genzyme Corp.);
Silicone polymer;
Polyurethanes;
Tetrathane (Dupont);
Polytetramethylene polymers;
Dacron;
Polyester woven fabric; and
Polycarbonated urethanes.

(d) Although the configuration of the memory-shaped linking connector prior to thermal deformation (as exemplified by Fig. 34A) may appear as a geometrically regular and coherent structure, there is no requirement or demand that either the detailed structure or overall appearance of any configured connector conform to these parameters.

Accordingly, it will be recognized and understood that the deformable and deployable shape-memory alloy structure need not take form as a completely encircling band or collar of thermoelastic material. To the contrary, L-shaped, T-shaped or H-shaped constructions of alloy material where the annular sidewalls do not overlap or join completely and/or where a gapped distance separates the arms of the linking connector are both permitted and envisioned. Moreover, although the isotropic cylindrical-shaped format of the connector illustrated by Fig. 34 is highly desirable in many instances, there is no requirement that the diameter of the connector structure prior to or after thermal deformation be constant or consistent over its entire axial length. Thus, anisotropic structures as well as isotropic constructions are intended and desirable. In this manner, the linking connector in its initial state prior to thermal deformation may have a variable internal diameter over the axial length of the article in which one open end may be either greater or lesser in size than the other open end; and there may be multiple increases and decreases in diameter size successively over the entire axial length of the connector itself. All of these variations in construction and structure are within the scope of the present invention.

To illustrate some of the more common variations and differences available and envisioned for a deformable in-situ and deployable at will linking connector intended for use with the present invention, the alternative embodiments illustrated by Figs. 35-37 are

1 provided. As shown within Figs. 35A and 35B, the initial shaped configuration for the
2 thermoelastic structure 330 appears as a cylindrical-shaped article or cuff having two open
3 ends 332, 334 and a rounded sidewall 336. The body of the sidewall 336 is an open
4 meshwork of closed wire loops 338, each closed wire loop being joined at multiple points
5 along its perimeter to at least one other closed wire loop -- thereby forming an open grid
6 meshwork. A notable feature of the connector construction within Fig. 35A is the outer
7 edges of the open ends 332, 334, each of which is formed by a closed wire loop which is
8 more easily bent and thermally deformed in-situ than the closed-loop meshwork in the
9 middle of the sidewall 336. In many instances, the availability of closed-loop edges 340,
10 342 provide an enormous benefit and advantage when thermal deformation of the linking
11 connector occurs in-situ. In addition, the first portion of the article shown by Fig. 35A has
12 been memory-shaped to deform substantially at the midline along the axis BB' such that the
13 upper sidewall upper portion 339 near the open end 332 and the edge 340 will deform in-
14 situ and flair outwardly as a consequence of placing the sidewall in a temperature
15 environment greater than about 25-35°C.

16 The result of thermal deformation in-situ at a temperature greater than about
17 25-35°C and deployment of the deformation in full is shown by Fig. 35B. The sidewall
18 upper portion 339 has become deformed and bent from the open end 332 to about the
19 midline axis BB'. However, the lower sidewall retainer portion 337 has remained
20 substantially unaltered overall its surface area from the midline axis BB' to the other open
21 end 334. The full deployment of this memory-shaped second configuration is illustrated by
22 Fig. 35B and represents the thermally deformed structure which attaches and secures a

1 tubular conduit to the internal lumen of an artery or vein in-vivo or into the internal cavity
2 of a hollow organ.

3 A third embodiment of a thermally deformable linking connector is illustrated by
4 Figs. 36A and 36B. As shown therein, the initial configuration for the deformable linking
5 connector 360 is illustrated by Fig. 36A and appears primarily as a series of coiled wires
6 368 whose overlapping and intersecting junctures have been fused together to make a
7 coiled unitary article. The deformable article has two open ends 362, 364 and an open
8 coiled sidewall 336 formed from the commonly fused coils of wire. The open lattice work
9 of coiled wires 368 provides the flexible and resilient meshwork suitable for achieving the
10 primary functions of the memory-shaped linking connector. The sidewall 366 also has
11 been pre-stressed along the middle axis CC' such that the uppermost sidewall portion 369
12 will become bent and deformed outwardly when exposed to an environment temperature
13 greater than about 25-35°C.

14 The consequence of placing the coiled linking connector in an ambient temperature
15 greater than about 25-35°C is shown by Fig. 36B. It will be appreciated that the memory-
16 shaped configuration of Fig. 36B is intended to be an in-situ generated event and result,
17 which can be deployed fully and completely at will. Thus, when fully deformed and
18 deployed, the flared out upper sidewall portion 369 has become bent at nearly a 90 degree
19 angle with respect to the lower retained sidewall portion 367; and the midline CC' will
20 generally serve as the axis of thermal deformation and deployed curvature for the coiled
21 linking connector.

22

1 A fourth alternative embodiment is provided by Figs. 37A and 37B in which a
2 thermally deformable cuff or band-shaped linking connector 380 is shown having two open
3 ends 382 and 384. In this instance, however, the sidewall 386 of the linking connector is
4 comprised of a solid sheet of alloy material. Two other features are also included in this
5 embodiment of the thermally deformable structure due to its construction using a solid
6 sheet of resilient material as the sidewall 386 for the linking connector. The sidewall 386
7 has been preferably pre-scored to form cross-hatched squares over the axial length of the
8 sidewall; and the pre-scored sidewall thus will deform far more easily and bend outwardly
9 along the scored lines of demarcation as shown when the linking connector is placed in an
10 ambient temperature greater than 25-35°C. Similarly, the sidewall material has been pre-
11 stressed along the midline axis DD' such that the upper most region 389 nearest the
12 opening 382 will become bent far more easily and deform in a controlled fashion when and
13 as required by the user.

14 The effect and consequences of placing the linking connector 380 in an ambient
15 environment whose temperature is greater than about 25-35°C is shown by Fig. 37B. The
16 uppermost sidewall portion 389 has thermally deformed into the memory-shaped second
17 configuration; and in the fully deployed state has become bent into a curved lip extending
18 outwardly from the midline axis DD'. However, the lower sidewall portion 387 has
19 remained substantially unchanged from its initial shape and size. The memory-shaped
20 deformation characteristics have thus generated an in-situ deformation and deployed
21 configuration most suitable for the attachment and securing of a tubular conduit in-vivo.

22

C. Superelastic Properties of the Linking Connector

2 It will be noted and appreciated also that the superelastic properties and use
3 characteristics of the linking connector as a structural entity exist in addition to and
4 concurrently with its thermoelastic properties and the ability to thermoelastically deform in-
5 situ on-demand. The superelastic properties of each linking connector in any of its many
6 structural formats typically include: (a) extreme elasticity in being able to return to its
7 original size and shape after having been stretched, compressed or altered in configuration;
8 (b) resilience in which the strain or energy created by a bending movement, force, torque
9 or shear force and applied to an elastic material is converted and does not cause
10 fragmentation, or cracking, or a mechanical breakdown of the material; and (c) malleability
11 in being able to be mechanically altered in shape or configuration (whether by rolling,
12 forging, extrusion, etc.) without rupture and without pronounced increase in resistance to
13 deformation. For purposes of practicing the present invention, all of the conventional
14 nickel-titanium metallic formulations which are shape-memory alloys as described herein
15 and characterized by Table 1 previously also are alloys which have and present superelastic
16 properties.

17 The value of employing linking connectors which exhibit superelastic properties in
18 addition to their demonstrable thermoelastic capabilities lies in the user's ability to control
19 separately and individually the physical deployment of the linking connector in its intended
20 memory-shaped configuration — in terms of choosing the precise timing, physical location,
21 and exact placement — after thermoelastic deformation and shape-memory reconfiguration
22 of the linking connector structure itself has been initiated. Thus, the act of and means for

1 controlled deployment — the spreading or arranging in appropriate position — for the
2 linking connector is separate and distinct from the thermal initiation and event of
3 thermoelastic deformation on-demand for the linking connector in-situ. The differences are
4 easily illustrated by easy reference to the introducer assemblies shown by Figs. 8B and 29
5 and to the method of introducing a prepared communication channel to a blood vessel or
6 hollow organ as illustrated by Figs. 9-14 and 30-33 respectively.

7 It is the user's choice and option, whether by personal intent or necessity, when to
8 allow the linking connector (then joined to the tubular conduit) to reach the critical
9 temperature required for thermal deformation to occur. However, once this critical
10 temperature is reached, thermal deformation and thermally caused alteration of the linking
11 connector transient structure into its permanent memory-shaped configuration will occur —
12 if and only if there is then sufficient physical space and ambient environment room for the
13 act of structural deformation to be performed fully and completely. Yet, if the linking
14 connector (and the joined tubular conduit) lie within a constrained and limited space and/or
15 a close boundary environment at the moment of thermoelastic initiation, then the thermally
16 initiated act of deformation and reconfiguration becomes restrained, incomplete, repressed,
17 and unfulfilled. No physical deployment and actual structural alteration into the shape-
18 memory configuration can or will occur unless and until the physical constraint(s) are
19 removed and the linking connector is released and has sufficient spatial freedom of
20 movement and rotation to complete the act of shape deformation in full and to present the
21 intended shape-memory configuration in an unconfined form.

22

1 Accordingly, if for example the critical temperature were reached for the linking
2 connector 82 as shown in Fig. 29, the initiation and event of thermoelastic deformation will
3 have occurred and begun in-situ while the linking connector was spatially confined within
4 the internal volume of the sheath 250; and the first sidewall portion 84 of the linking
5 connector would be physically constrained and be prevented from deforming in full by the
6 limited space and physical obstruction created by the interim diameter size of the
7 volumetric sheath 250. Similarly, as seen in Fig. 3D, the first sidewall portion 84 remains
8 restrained and confined by being positioned within the recessed furrow 267 of the
9 perforating headpiece 230 such constraint and physical confinement is removed and the
10 linking connector released from the constrained setting for an at-will controlled deployment
11 and proper positioning by the acts shown in Fig. 31.

12 It is essential therefore to recognize and appreciate that while thermoelastic
13 deformation in-situ for the linking connector occurred on-demand — that is, within the
14 volumetric sheath of the introducer assembly, the act of physically deploying the
15 thermoelastically activated linking connector was purposefully delayed and the act of
16 thermal deformation itself was restrained and controlled spatially until the moment the user
17 chose for most effective anatomic placement and appropriate local positioning for the
18 memory-shaped configuration. Clearly, it is the superelastic properties of the alloy
19 formulations which provide the user with the capability not only to separate the individual
20 act of thermoelastic deformation in-situ on-demand from the act of spatial deployment and
21 constrained control at will of the spatial deployment of the thermoelastically deforming
22 linking connector; but also to allow the user to choose for himself the precise timing,

physical location, and proper placement for the deployment of a thermoelastically deforming linking connector as a direct consequence and result of being able to control such spatial deployment.

D. The Tubular Conduit

The tubular conduit comprises any biocompatible tube, sleeve, channel, flow line, hose, piping, duct, or configured outlet which allows and provides an unobstructed conveyance and transport of fluid matter through its interior space. By definition, the term "fluid matter" includes and encompasses any and all flowing solids, liquids, and/or gases as well as any mixture of these materials without regard to their chemical composition, degree of purity, amassed volume or quantity, and/or medical significance or value.

The tubular conduit has at least one tubular wall of fixed axial length; has at least one proximal end for entry; has at least one distal end for egress; and has at least one internal lumen of a volume sufficient to allow for on-demand passage therethrough of any fluid matter.

Many different types and constructions of tubular conduits are conventionally known and used; and a wide range and variety of tubular conduits are available which are extremely diverse in shape, design, and specific features. All of the essential requirements of a tubular conduit exist as conventional knowledge and information; and all of the information regarding conduit design and described in summary form hereinafter is publicly known, widely disseminated, and has been published in a variety of texts. The

1 reader is therefore presumed to be both familiar with and have an in-depth knowledge and a
2 general understanding of conventional tubular conduits.

3 A number of specific types of tubular conduits are known today; but for purposes
4 of practicing the present invention, a number of newly designed or specifically designed
5 conduits of varying lengths and sizes suitable for use are expected and intended to be
6 developed and manufactured subsequently. Equally important, minor modifications of the
7 presently existing general categories of tubular conduits are equally appropriate and are
8 expected to be found suitable for use when practicing the present invention.

9 Merely representative of tubular conduits in general without regard to their specific
10 past usages or intended applications, are those illustrated by Figs. 38-47 respectively. As
11 exemplified by Fig. 38, a tubular conduit 550 is seen having a tubular wall 552 of fixed
12 axial length; having two proximal open ends 554 and 556 which together generate the
13 egress and exit to the interior of the conduit, a single internal lumen 558.

14 Another variation commonly known is illustrated by Fig. 39 which shows a
15 conduit 560 having a central tubular wall portion 572 of fixed axial length; having two or
16 more branches 574, 576 respectively which collectively form the proximal ends 596, 594
17 for entry into the internal volume of the conduit; and a single unbranched end 580. It will
18 be appreciated and understood that Figs. 38-47 are presented merely to show the overall
19 general construction and relationship of parts present in each flexible tubular conduit
20 suitable for use with the present methodology.

21 Also, in accordance with established principles of conventional construction, the
22 axial length of the conduit may be composed of one or several layers in combination. In

1 most multilayered constructions, one hollow tube is stretched over another to form a bond;
2 and the components of the individual layers determine the overall characteristics for the
3 conduit as a unitary construction. Some multilayered conduit structures comprise an inner
4 tube of teflon, over which is another layer of nylon, woven Dacron, stainless steel or
5 nitonol braiding. A tube of polyethylene or polyurethane is then heated and extruded over
6 the two inner layers to form a bond as the third external layer. Other constructions may
7 consist of a polyurethane inner core, covered by a layer of stainless steel or nitinol
8 braiding, and a third external jacket layer formed of polyurethane.

9 Several examples of basic conduit construction and design are illustrated by Figs.
10 40-47 respectively. Figs. 40A and 40B are perspective and cross-sectional views of a
11 single tubular wall considered the standard minimum construction for a conduit. Figs. 41A
12 and 41B are perspective and cross-sectional views of a thin-walled design for a single layer
13 extruded conduit. In comparison, Figs. 42A and 42B are perspective and cross-sectional
14 views of a standard multilayered construction having a braided stainless steel midlayer in
15 its structure. Finally, Figs. 43A and 43B are perspective and cross-sectional views of a
16 thin-walled design for a multilayered conduit with a braided stainless steel middle layer.

17 In addition, a number of different dual-lumen conduits are known today. These
18 differ in size and spatial relationship between their individual lumens. The construction
19 difference are illustrated by Figs. 44-47 respectively which show different dual-lumen
20 constructions for four tubular conduits having similar or identical overall diameter size.

21 As shown therein, Fig. 44 shows a dual-lumen conduit 630 wherein a first external
22 tubular wall 632 provides an outer lumen volume 634 into which a second internal tubular

1 wall 636 has been co-axially positioned to provide an inner lumen volume 638. Clearly,
2 the construction of conduit 630 is a co-axial design of multiple tubular walls spaced apart
3 and co-axially spaced but separate internal lumens of differing individual volumes.

4 In comparison, Fig. 45 shows a second kind of construction and design by dual-
5 lumen conduit 640 having a single external tubular wall 642; and an centrally disposed
6 inner septum 644 which divides the interior tubular space into two approximately equally
7 lumen volumes 646 and 648 respectively. Thus, in this construction, the diameter, length,
8 and volume of internal lumen 646 is effectively identical to the diameter, length and
9 volume of internal lumen 640; and both of these exist and are contained within a single,
10 commonly-shared, tubular wall.

11 A third kind of construction is illustrated by Fig. 46 and shows an alternative kind
12 of construction and design. As seen in Fig. 46, the dual-lumen conduit 656 has a single
13 external tubular wall 652; and contains an asymmetrically positioned internal divider 650
14 which divides the interior tubular space into two unequal and different lumen volumes 650
15 and 658 respectively. Thus, in this alternative construction, the discrete volume of internal
16 lumen 650 is markedly smaller than the volume of the adjacently positioned internal lumen
17 658; and yet both of these internal lumens 650 and 658 exist in, are adjacently positioned,
18 and are both contained within a commonly-shared single tubular wall.

19 A fourth construction and design for a dual-lumen conduit is presented by Fig. 47
20 which shows a conduit 660 having a single external tubular wall 662 of relatively large size
21 and thickness. Within the material substance 668 of the tubular wall 660 are two discrete
22 bore holes 664 and 666 of differing diameters which serve as two internal lumens of

1 unequal volume. Internal lumen 664 is clearly the smaller while internal lumen 666 is far
2 greater in spatial volume. Yet each internal lumen volume 664 and 666 is adjacent to the
3 other, lies in parallel, and follows the other over the axial length of the conduit.

4 In general, the tubular body conduit is flexible over most of its length and may
5 have one or more bends or curves towards the ends. Conventional practice also permits
6 using a number of differently formed ends or tips which vary in design and appearance.
7 Accordingly, for purposes of practicing the present invention, any construction of the
8 tubular conduit whether having one or more curves, or none; and whether or not there is
9 more than one designed portal for exiting or entering the lumen or multiple lumens are all
10 considered conventional variations in construction design. Any and all of these designs and
11 constructions are therefore deemed to be encompassed completely and to lie within the
12 general scope of construction suitable for use with the present invention.

13

14 1. Vascular Conduit Bypass Graft Material

15 Two major sources of conduits suitable for use as a vascular bypass graft are
16 presently known and available. These are: synthetic prosthetic channel sections and
17 previously excised blood vessel segments.

18 The choice of graft conduit is crucial to the success of coronary artery bypass
19 grafting surgery (CABG) because the patency of a coronary conduit is closely associated
20 with an uneventful postoperative course and a better long-term patient survival. The
21 standard vascular conduits used for CABG are excised blood vessel segments taken from
22 the greater saphenous vein (GSA) or another leg or arm vein. An excellent substitute

1 conduit for coronary bypass operations that can be available on demand is certainly the
2 desire of every practicing cardiac surgeon. However, virtually every synthetic alternative
3 to arterial conduits or autologous fresh saphenous vein conduits has proved disappointing.
4 Fortunately, patients with absolutely no autologous conduit are uncommon. Circumstances
5 exist, however, that often necessitate the use of alternative synthetic conduits such as young
6 hyperlipemic patients; as absent or unsuitable autologous internal mammary artery and
7 greater saphenous vein as a result of previous myocardial revascularization, peripheral
8 arterial reconstruction; and varicose vein ligation procedures. In the present era of
9 increasing numbers of repeat coronary revascularizations, approximately 15% of patients
10 requiring CABG are now in need of alternative synthetic conduits.

11

12 a. Synthetic Conduits

13 The desired characteristics of synthetic conduits used as bypass grafts are
14 nonimmunogenicity, easy availability and storage, less risk of kinking (due to its stiffness),
15 a less turbulent flow (due to uniform diameter), and an absence of branches.

16 The medical value of synthetic conduits as bypass grafts in-vivo has been
17 substantially investigated. See for example: Foster *et. al.*, Circulation **79** (Sup 1):
18 134-139 (1989); and Canver, C.C., Chest **108**: 1150-1155 (1995); and the other references
19 cited below. A summary review of the recent reports evaluating these conduits thus is in
20 order.

Historically, Sauvage and associates in 1976 [J. Thorac. Cardiovasc. Surg. 72; 418-421 (1976)] described the placement of a 4.0-cm long, 3.5-mm diameter knitted

1 Dacron filamentous vascular prosthesis as an interposition graft between the aorta and right
2 coronary artery during repair of a vascular aneurysm of the ascending aorta in an adult.
3 The graft was demonstrated to be patent by angiography 16 months after operation. A
4 literature search at the time found only two other prior reports of successful aortocoronary
5 grafting with synthetic conduits, both involving children with congenital coronary defects.
6 Two factors present in all three cases that were suggested as promoting long-term patency
7 were that only short segments of prosthetic graft were placed, and that they were implanted
8 as interposition grafts from the end of the coronary artery to the aorta.

9 The initial results of CABG with expanded polytetrafluoroethylene (PTFE) (Gore-
10 Tex. W.L. Gore and Associates, Elkton, Maryland) grafts were encouraging; however, this
11 impression was based on single-case reports or series with small numbers of patients.
12 Molins and co-authors in 1978 [J. Thorac. Cardiovasc. Surg. **75**: 769-771 (1978)]
13 presented a patient in whom they had constructed a bypass to the distal right coronary
14 artery with a 4.0 mm diameter PTFE graft, found patent on catheterization 3 months after
15 surgery. Also, Yokoyama and associates in 1978 [J. Thorac. Cardiovasc. Surg. **76**:
16 552-555 (1978)] described five aortocoronary bypass patients in whom 3.0-5.0-mm PTFE
17 grafts had been used. Four of five of these grafts were open on restudy 3-6 months
18 postoperatively. Subsequently, Islam and colleagues in 1981 [Ann. Thorac. Surg. **31**: 569-
19 573 (1981)] reported that a 6-mm diameter PTFE graft used for aorta-to-right coronary
20 artery bypass remained widely patent on repeat angiography 18 months after surgery.

21 An indication of the early and midterm results of CABG with PTFE grafts was
22 provided in the 1981 report of Sapsford and associates [J. Thorac. Cardiovasc. Surg. **81**:

1 860-864 (1981)]. Twenty-seven coronary bypasses were constructed in 16 patients with
2 4.0-mm PTFE grafts. Eleven patients were restudied at 3 months after surgery, and a 61%
3 (11 of 18) graft patency rate was found, in six patients who had repeat angiography 12-29
4 months after CABG, six of nine PTFE grafts were open. Then, Murta and co-authors in
5 1985 [Ann. Thorac. Surg. **39**: 86-87 (1985)] detailed a single case experience where two
6 4.0-mm diameter PTFE aortocoronary grafts remained present 53 months postoperatively.
7 More recently, Chard and associates reported in 1987 [J. Thorac. Cardiovasc. Surg. **94**:
8 132-134 (1987)] long-term patency results with PTFE aortocoronary grafts. Using both
9 end-to-side and multiple, sequential, side-to-side anastomoses, they constructed a total of
10 28 distal coronary grafts in eight patients. Patency rates on repeat angiography were 64%
11 (18 of 28) at 1 year, 32% (9 of 28) at 2 years, 21% (6 of 28) at 3 years, and 14% (4 of 28)
12 at 45 months.

13 The choices of materials recognized as being suitable for the making of a
14 biocompatible synthetic conduit are quite limited. These are provided by Table 3 below.
15

16 b. The Excised Blood Vessel Segment

17 A variety of blood vessel segments excised from the vascular system in-vivo are
18 suitable for use as bypass graft conduits. A representative, but incomplete, listing is
19 provided by Table 4 below.
20

21

Table 3: Synthetic Conduit Materials

Synthetic Substances

Dacron (knitted or woven) polymer;
Polytetrafluoroethylene or "PTFE" (knitted or woven);
Impra;
Teflon polymer;
Kevlar polymer;
Polycarbonated urethan;
Silicone;
Thermoplastic polymers and elastomers; and
Collagen, human or bovine.

Table 4: Vascular Conduits For Bypass Grafting

Venous Conduits

(a). Autologous vein conduits.

Greater saphenous vein segments;

Lesser saphenous vein segments;

Upper extremity (cephalic and basilic) vein segments.

(b). Nonautologous vein conduits.

Umbilical vein segments;

Greater saphenous vein homografts.

Arterial Conduits

(a). Autologous arterial conduits.

Internal mammary artery segments;

Right gastroepiploic artery segments;

Inferior epigastric artery segments;

Radial artery segments;

Splenic artery segments;

Gastroduodenal artery segments;

Left gastric artery segments;

Intercostal artery segments.

(b). Nonautologous arterial conduits.

Bovine internal thoracic artery segments.

1 The preferred sources of blood vessels suitable for use as a vascular bypass graft
2 are the saphenous veins. These veins constitute the superficial veins of the lower
3 extremities and comprise both the greater (or long) saphenous and the lesser (or short)
4 saphenous veins. Anatomically, the long saphenous vein begins on the medial side of the
5 foot and ends in the fermoral vein below the inguinal ligaments; and the short saphenous
6 vein begins behind the lateral malleous and runs up the back of the leg to end in the
7 popliteal vein. However, if the saphenous veins of the particular patient are unsuitable or
8 unavailable for any reason, either the cephalic or the basilic veins are very acceptable
9 substitutes for use as a vascular bypass conduit. However, if these leg or arm veins are not
10 available, synthetic or other biologic materials may also be used as substitutes.

11 The medical procedure to isolate and excise the saphenous vein of choice is
12 conventionally known and considered a routine surgical technique. The saphenous vein is
13 harvested under general anesthesia. An incision is first made in the medial malleolus,
14 where the saphenous vein is often dilated. The saphenous vein is identified and then
15 dissected with a single incision made along its course with scissors. Branches are doubly
16 clamped with hemostatic clips and divided. The saphenous vein is then freed up and
17 removed from the leg. The leg wound is closed with subcutaneous sutures and Steristrip
18 adhesive over the incision. The vascular segment is prepared on a separate sterile table
19 with adequate light and loupes, and branches are selectively ligated with 4-0 silk. An oval-
20 tip needle on a syringe is inserted into the graft to gently dilate it by administering a
21 balanced electrolyte solution (pH 7.4, chilled to 7° to 10°C) and 10,000 units/liter of
22 heparin. A valvulotome is inserted into the vein graft segment and the valves clipped with

1 a 3-mm right-angle stainless steel instrument with a highly polished ball tip on the right
2 angle. The knife edge is protected and sharply splits the cusp, causing valvular
3 incompetence. Measurements for the approximate lengths of the grafts may be made with
4 umbilical tapes, and the appropriate lengths may be chosen before it is sewn to the cuff and
5 coronary arteries.

6

2. Tubular Conduits Suitable For Use As Access Ducts

8 In the main, many of the same tubular conduits formulated and composed of
9 synthetic materials may be used as access ducts when joined to a hollow organ.
10 Accordingly, these same materials previously listed within Table 4 herein as synthet
11 conduit materials are most suitable and desirable for use as access duct conduits.

12 In addition, in order to improve the performance of the access duct conduit when
13 joined and secured into the internal spatial volume a hollow organ in-situ, it is most
14 desirable to provide the exterior surface of the access duct with a hydrophilic coating or to
15 mold the entirety of the exterior surface at least using a hydrophilic plastic composition.
16 By providing the access duct with appropriate hydrophilic properties, the tubular conduit
17 will have a lower coefficient of friction and will more easily slide through the aperture to
18 be made in the body cavity wall.

19 These highly desirable hydrophilic coatings or plastics are substantially non-reactive
20 with respect to living tissue and are non-thrombogenic when placed in contact with blood
21 or other body fluids. Appropriate hydrophilic coatings therefore would include
22 polyvinylpyrrolidone--polyurethane or polyvinylbutyrol interpolymers as described in U.S.

1 Patent Numbers 4,100,309 and 4,119,094. In addition, appropriate molding compounds
2 which could alternatively be applied as coatings, include hydrophilic polymer blends with
3 thermoplastic polyurethane or polyvinylbutyrol and hydrophilic polyvinylpyrrolindone or
4 other poly(N-vinyl lactans) as described in U.S. Patent Numbers 4,642,267 and 4,847,324.
5 Such hydrophilic coatings will typically reduce the coefficient of friction by over sixty
6 percent for metals and can reduce the coefficience of friction for plastics by over ninety
7 percent.

8

9 The present invention is not to be restricted in form nor limited in scope except by
10 the claims appended hereto.

11